IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KONINKLIJKE PHILIPS N.V. and IP2IPO INNOVATIONS, LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 24-206-CFC
OPSENS INC., OPSENS MEDICAL, OPSENS MEDICAL INC., and HAEMONETICS CORPORATION,	)	
Defendants.	)	

JOINT CLAIM CONSTRUCTION BRIEF

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EXHIBIT	DESCRIPTION
A	’463 Patent File History (Excerpted)
B	’463 Patent Response to Office Action Issued September 19, 2017
C	’463 Patent Initial Patent Application
D	’463 Patent Office Action Issued September 19, 2017
E	’463 Patent Notice of Allowance
F	’463 Patent Response to Office Action Issued July 14, 2016
G	’463 Patent Office Action Issued January 11, 2017
H	’463 Patent Office Action Issued July 14, 2016
I	’463 Patent Applicant-Initiated Interview Summary (August 10, 2016)
J	’463 Patent Applicant-Initiated Interview Summary (April 28, 2017)
K	’463 Patent Response to Office Action Issued January 11, 2017
L	’463 Patent Final Office Action Issued June 15, 2020
M	’463 Patent Response to Final Office Action Issued June 25, 2020
N	’463 Patent Applicant-Initiated Interview Summary (August 25, 2020)
O	United States Patent Application Publication No. 2003/019400
P	USPTO Claim Drafting Conference Presentation

I. INTRODUCTION

A. Plaintiffs' Opening Introduction

U.S. Patent No. 10,912,463 (D.I. 41, Ex. A ("the '463 Patent")) claims a novel system for diagnosing the severity of a blood vessel blockage (also called a "stenosis") in coronary patients. *See* '463 Patent, 1:17–40. The system comprises structure that calculates a "pressure ratio," which in the coronary field refers to the ratio of the blood pressures in a patient's blood vessel on (1) the far side of a stenosis ("distal pressure") and (2) the near side of the stenosis ("proximal pressure"). *Id.*, 1:30–33. By averaging these two blood pressures, a physician can see the drop-off in blood pressure after the stenosis and, by proxy, the severity of the blockage in a patient's blood vessel. *Id.*, 16:45–55.

The patented system, unlike prior systems, does not require the use of adenosine or other vasodilating drugs to evaluate the severity of the stenosis. These drugs can assist in measuring the pressure gradient (blood flow restriction) across a stenosis but can be uncomfortable to patients. *Id.*, 2:7–11. Instead, the patented system only uses pressure measurements from a specific sub-portion of the cardiac cycle such as diastole (i.e., when the heart relaxes). Philips has used its patented system using a hyperemia-free pressure ratio—marketed under the name "iFR"—to significant commercial success. D.I. 1, ¶ 29. The Defendants in this case have launched a copycat system using a pressure ratio called "dPR" that—like iFR—

avoids the prior art need for adenosine or other drugs by performing calculations during a sub-portion of the cardiac cycle.

Defendants have proposed two claim constructions for the '463 Patent that are directed towards the same end: the Defendants seek to write their non-infringement arguments into the claims. Defendants' construction would amend the claims of the '463 Patent to exclude embodiments in the patent and narrow the scope of the claimed structure for calculating a pressure ratio. *See* D.I. 41, 2. The asserted claims in this case are open-ended "comprising" claims, yet Defendants' construction seeks to exclude from these claims' scope a system that practices the claimed system claims but which—in addition to the claimed system elements—may also include additional supported functionality such as averaging or normalization. *Id.* For example, Defendants' construction would foreclose any additional processing after the calculation of the pressure ratio recited in the claims and limiting the pressure ratio calculations to using pressure measurements from a *single* cardiac cycle, rather than, for example, averaging measurements over multiple cardiac cycles to reduce noise and variability. *Id.*; *see* '463 Patent, 27:19–32. The Defendants' proposed claim narrowing would nonsensically exclude multiple dependent claims directed towards averaging from the scope of the independent claims in addition to excluding multiple embodiments in the patent that expressly envision averaging over multiple cardiac cycles. '463 Patent, Cls. 20, 21, 28, 29.

Not only are Defendants' proposed constructions improper because they would introduce the legal error discussed above, but construction is also unnecessary because neither term, "calculate a pressure ratio" or "output … the calculated pressure ratio," requires construction. The claims expressly explain how the pressure ratio may be calculated. To the extent they should be construed, they should be construed in a manner that clarifies their meaning—not arbitrarily narrowing them to aid the Defendants' non-infringement case.

B. Defendants' Answering Introduction

Defendants OpSens Inc., OpSens Medical, OpSens Medical Inc., and Haemonetics Corporation (collectively, "Defendants") propose only two claim terms of U.S. Patent No. 10,912,463 (the "'463 Patent") for construction. Plaintiffs Koninklijke Philips N.V. and IP2IPO Innovations, Ltd. (collectively, "Plaintiffs") unsurprisingly seek to avoid construction of those two terms or, alternatively, provide overbroad constructions of the terms that are not aligned with the intrinsic record. Defendants' proposed constructions, on the other hand, comport with the claim language, specification, and prosecution history.

Despite their conflicting constructions, the parties appear to largely agree on most issues. *First*, Defendants agree with Plaintiffs' description of the claimed

invention and patented technology.[1] *Second*, the parties agree that "a cardiac cycle," standing alone, could refer to one or more cardiac cycles. *Third*, the parties agree "[t]he plain language of the claims unambiguously describes the way in which 'a pressure ratio,' is 'calculate[d],' giving the term metes and bounds for how the calculation is performed." Section IV.A.1.a, *infra*. Overall, the parties' understanding of the patented claims are strikingly similar.

The slight differences in the parties' positions—and respective constructions—lay bare the parties' differing approaches to claim construction. Defendants' proposed constructions are rooted in the claim language itself and find support both in the specification and arguments and amendments made during prosecution.

For example, the plain language of the claims make clear that the "calculate a pressure ratio for . . . a cardiac cycle" term is limited to the calculation occurring during only one cardiac cycle. The dependent claims recite a system which is "further configured to" calculate the pressure ratio for a plurality of cardiac cycles. Thus, this added limitation—notably absent from the independent claims—is

[1] While Defendants agree with Plaintiffs' general characterizations of the technology, Defendants take issue with Plaintiffs' aspersions of Defendants as "copycats," an issue not relevant to claim construction. A far cry from being a copycat, Defendants have independently developed their own intravascular system utilizing an entirely separate hyperemic index to assess the severity of a stenosis.

presumed to be additional subject matter. This meaning aligns with the specification, which discloses pressure ratios calculated for only one or for a plurality of cardiac cycles. It is also consistent with the prosecution history, where patentee amended its claims to move the recitation of a plurality of cardiac cycles from the independent claim into a dependent claim, reciting an additional limitation.

The same is true of Defendants' proposed construction for the term "output . . . the calculated pressure ratio". The parties agree that the claim language explicitly and unambiguously defines the calculated pressure ratio. Defendants' proposed construction, which is in consonance with the defined equation, is consistent with the patent's disclosure of numerous other equations, similarly defined. The term's meaning is reinforced by the prosecution history in which patentee incorporated the explicit calculation into the independent claims to overcome a prior art rejection, abandoning the broad scope it now seeks to recapture.

Plaintiffs' proposed constructions are overreaching. For both terms, Plaintiffs seek to expand the scope of the independent claims to cover limitations that are *added for the first time* in the dependent claims. Moreover, Plaintiffs selectively choose to focus on certain claim terms (*e.g.*, "comprising") while ignoring other claim terms (*e.g.*, "further configured" and "calculated as") which provide context for the terms' meanings. Plaintiffs cannot use claim construction as an opportunity to rewrite the claims in a manner that Plaintiffs wish they had been written. Instead,

Courts interpret the claims as they appear in the '463 Patent when viewed in the context of the specification and prosecution history.

Defendants respectfully request the Court adopt their proposed constructions of the identified claim terms.

C. Plaintiffs' Reply Introduction

Defendants' proposed constructions are a transparent attempt to do exactly what the law forbids: rewrite the claims to fit a litigation strategy, not the intrinsic record. The overwhelming intrinsic evidence—dependent claims, specification, and Examiner statements—all confirm that the independent claims are inclusive of multi-cycle calculations and additional processing. Yet Defendants contend that these features are covered only by the dependent claims and are categorically *excluded* from the independent claims—insisting that "a" means "*only* one" and that "calculated as" should be construed as "calculated *only* as."

The patentee never disclaimed the scope that Defendants now seek to exclude through their two proposed constructions. The amendments Defendants rely on were proposed by the Examiner and later adopted in all independent claims to address 35 U.S.C. § 101 concerns—not to overcome prior art based on the number of cardiac cycles or additional processing steps like averaging, rounding, or normalization. *See* Section IV.B.3.c*, infra*; *see also* Section II, *infra* (giving an overview of '463 patent).

If accepted, Defendants' constructions would read out preferred embodiments, contradict the claims' open-ended nature, unjustifiably impose negative limitations that go beyond anything actually surrendered during prosecution, and create unnecessary ambiguity. By contrast, Plaintiffs' constructions adhere to the plain language of the claims, align with the intrinsic evidence, and reflect the scope the patentee preserved during prosecution.

D. Defendants' Sur-Reply Introduction

Plaintiffs must accept the claims as written—not as Plaintiffs wish patentee had written them. To divorce the words in the claim from their meaning, Plaintiffs point to inapposite cases (pertaining to validity and reissue determinations), ignore the differences in word choice among claims, and downplay amendments made during prosecution to refine and position the claims for allowance. Moreover, Plaintiffs argue at length that Defendants have failed to meet the high standard of proving disclaimer, but Plaintiffs are shadow boxing with an argument Defendants never made.

Instead, the claim language, as supported by the descriptions in the '463 Patent specification and statements during prosecution, provide clear meanings for the two disputed claim terms. Defendants' proposed constructions are inconsonance with those meanings. Plaintiffs' attempts at diversion should be rejected. Defendants'

proposed constructions, on the other hand, which align with the actual claim language, specification, and prosecution history, should be adopted.

Defendants respectfully request the Court adopt their proposed constructions of the identified claim terms.

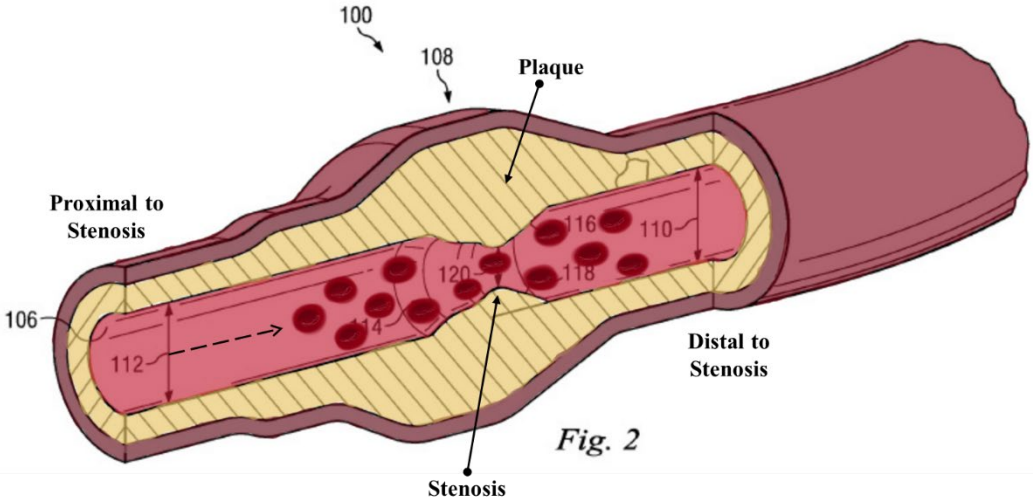
II. PLAINTIFFS' OVERVIEW OF THE '463 PATENT

The asserted claims of the '463 Patent are directed to devices, systems, and methods configured to assess the severity of a condition known as stenosis in a subject's coronary arteries without requiring the administration of an uncomfortable drug referred to as a hyperemic agent. *See* D.I. 41, Ex. A (listing asserted claims); '463 Patent, Cls. 1, 11, 26.

The human heart is powered by an intricate network of blood vessels that work tirelessly to deliver oxygen-rich blood throughout the body. Among these, the coronary arteries play a critical role, supplying blood directly to the heart muscle. But when these arteries become narrowed or blocked—a condition known as stenosis—the heart struggles to get the oxygen it needs. '463 Patent, 6:43–61.

A. Stenosis

Stenosis is a common complication of coronary artery disease (CAD), caused by plaque buildup along the walls of arteries. '463 Patent, 6:43–61. Over time, this narrowing restricts blood flow, leading to symptoms like chest pain (angina), shortness of breath, and even life-threatening conditions, such as heart attacks. *Id.*, Fig. 2.



Annotated Figure 2 – Coronary Artery Disease

See id., Fig. 2 (annotated) (showing coronary artery disease). When a stenosis is severe enough, doctors may recommend a procedure called percutaneous coronary intervention (PCI) to restore proper blood flow. PCI involves threading a catheter through the patient's blood vessels to the blockage site, where techniques like balloon angioplasty (inflating a tiny balloon to widen the artery) or stent placement (inserting a small mesh tube to keep the artery open) can be used. *Id.*, 1:28–40.

B. Fractional Flow Reserve

Prior to the claimed invention, Fractional Flow Reserve (FFR) was one of the most widely used physiological indices (calculated measures) to assess the severity of a coronary artery stenosis. FFR measures blood pressure close to the heart (proximal to; Pa) and far away from the heart (distal to; Pd) while the patient is under a hyperemic drug (a vasodilating agent that dilates the patient's blood vessels) and computes a ratio: Pd/Pa for the entire cardiac cycle—the period of heart contraction (systole) and relaxation (diastole). D.I. 1, ¶ 27. FFR is dependent on achieving hyperemia, which is "a stressed state of the patient's heart" in which blood vessels are their most dilated and blood flow is maximized to ensure an accurate assessment of pressure gradients. '463 Patent, 12:32–35. A hyperemic state is required because, under normal testing conditions, vascular resistance fluctuates due to the contraction and relaxation of blood vessels in response to factors such as heart rate, respiration, and metabolic demand. *Id.*, 1:44–51. These fluctuations can obscure the true impact of the stenosis on blood flow. *Id.* ("As a result [of these factors], for an effective calculation of FFR within the coronary arteries, it is necessary to reduce the vascular resistance within the vessel."). By inducing this stressed state, vasodilators, such as adenosine, force the blood vessels to reach their maximum diameter, minimizing variation in resistance and allowing for consistent pressure measurements. *Id.*, 1:28–2:25, 12:54–58, Figs. 5–8.

While vasodilating drugs are effective in inducing hyperemia, their use presents significant clinical and practical challenges, making FFR measurements cumbersome or impractical in certain cases. *Id*., 1:59–2:25. Adenosine can cause distressing side effects, such as chest pain, shortness of breath, nausea, dizziness, hypotension (low blood pressure), or bradycardia (slow heart rate), which are only compounded if adenosine "need[s] to be applied multiple times … to obtain FFR measurements." *Id*., 2:7–11. These side effects are not only uncomfortable but can also pose serious health risks for patients with existing cardiovascular conditions. *Id.* Even patients with no history of pre-existing conditions can face life-threatening complications, especially if adverse side effects are unanticipated by the physician. *Id*., 2:14–17 ("not all patients respond as expected … it is difficult to identify these patients before administration of the hyperemic agent"). Furthermore, adenosine administration is "expensive, and time consuming," requiring specialized preparation and sometimes central venous access for intravenous delivery (i.e., placing a catheter into a large vein to allow for continuous infusion of adenosine directly into the bloodstream). *Id*., 1:59–2:25. These logistical hurdles can prevent its administration to a patient, lead to delays in interventional procedures, or discourage physicians from using FFR altogether. *Id*., 1:66–2:2.

C. Non-Hyperemic Pressure Ratios

Given the limitations of hyperemic pressure ratios such as FFR, there was a strong clinical demand for a physiological index that would not require vasodilating drugs. '463 Patent, 2:12–25. The claimed system comprises an apparatus for calculating a hyperemia-free pressure ratio used to assess stenosis, one embodiment of which is marked by Philips under the name of "iFR," short for "Instantaneous Wave-Free Ratio." D.I. 1, ¶ 29. Unlike FFR (Pd/Pa under adenosine), where pressure measurements are taken during the entire cardiac cycle this system calculates a pressure ratio of distal and proximal pressure measurements obtained during a select diagnostic window within a cardiac cycle. This diagnostic window can be selected according to criteria identified in the patent where the microvascular resistance is inherently stable (i.e., the extent to which the small blood vessels in the heart restrict blood flow remains fairly constant), reducing or eliminating the need for drug-induced hyperemia. '463 Patent, 12:8–19, 12:54–58.

Rather than use every pressure measurement received from a patient, the diagnostic window collects pressure measurements from only the portion(s) of the cardiac cycle that allow for a stable pressure ratio. In particular, the invention can employ a period in the cardiac cycle when coronary resistance is "naturally reduced and relatively constant," such as diastole. *Id.*, 12:59–13:15; D.I. 1, ¶ 29. While Philips' iFR utilizes the "wave-free period" of the cardiac cycle, which is described

in the '463 Patent, the diagnostic window can also encompass part or all of diastole.'463 Patent, 17:49–18:58, 19:47–67, 27:33–29:27. The '463 Patent describes the process for identifying the diagnostic window through various means such as physiological markers (e.g., dicrotic notch, velocity, peak pressure of the cardiac cycles, the start or end of diastole, ventricularization point, and/or stable flow period). *Id.*, 19:27–24:54, Fig. 11. By aligning the proximal and distal pressure waveforms and extracting data only during this diagnostic window, the system may evaluate coronary stenoses similarly to FFR without the need for a vasodilator. *Id.*

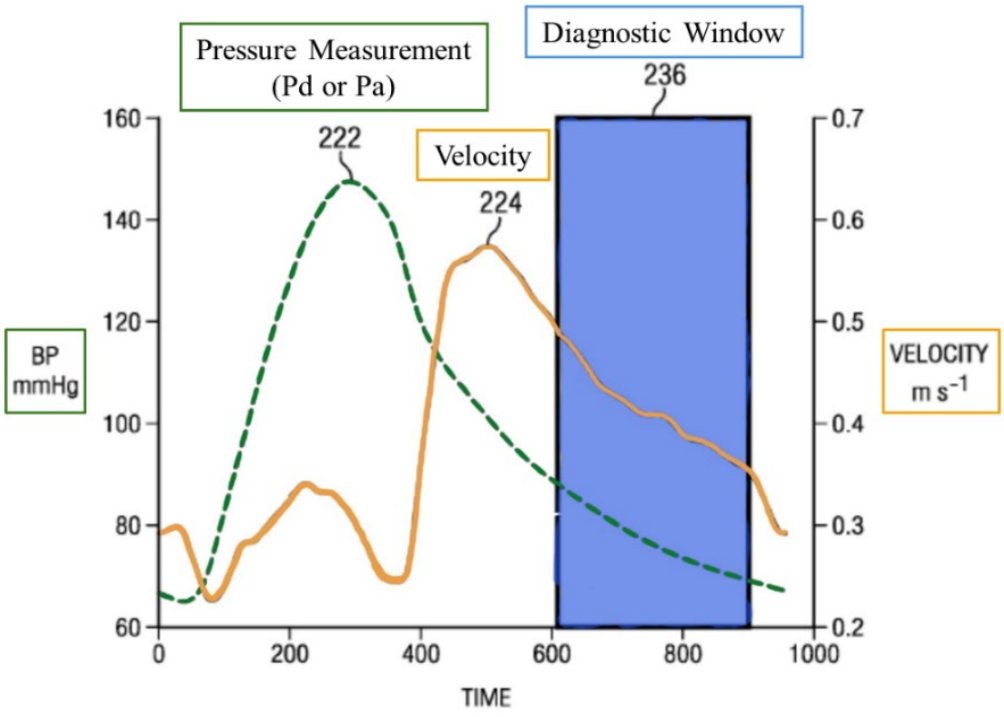


Fig. 11

Annotated Figure 11 – Illustrative Selection of a Diagnositc Window Based on Blood Flow Velocity

See id., Fig. 11 (annotated) (showing illustrative selection of a diagnostic window based on blood flow velocity). Since coronary blood flow is influenced by numerous factors, including heart rate fluctuations, respiration, and changes in microvascular resistance, pressure signals present difficulties in obtaining a reliable pressure ratio. The '463 Patent addresses this issue by disclosing multiple methods for ensuring accurate calculation of the pressure ratio, including the use of a "diagnostic window" in which pressure measurements are taken, in addition to various normalization, filtration, and advanced computational techniques.

For example, one of the disclosed methods involves temporal normalization, in which pressure measurements for the pressure ratio are taken at different points within a cardiac cycle across multiple cardiac cycles to ensure pressure measurements remain comparable. *Id.*, 27:4–28:46 ("In other instances, the pressure ratio calculations are performed for multiple cardiac cycles."). Another approach enhances signal clarity from the catheter by incorporating filtration techniques to eliminate artifacts and noise that can interfere with accurate pressure ratio calculations. *Id.*, 25:61–26:18 ("[D]uring data acquisition, there will often be a delay between the distal pressure measurement signals and the proximal pressure measurement signals due to hardware signal handling differences … the differences … can be due to signal processing differences (such as filtering techniques)."). The patent further describes temporal alignment techniques, such as time-shifting

algorithms that adjust for any delays between Pd and Pa introduced by catheter positioning. *Id.*, 25:39–26:56 ("FIG. 32 illustrates a temporal adjustment of the distal pressure measurement relative to the proximal pressure measurement."). *Id.*, Fig. 32.

Since its introduction, iFR has gained widespread clinical acceptance as a leading alternative to FFR. D.I. 1, ¶¶ 29–32. The industry wide adoption of iFR underscores its impact as the "reference standard" for pressure-based physiological assessments. Ex. C to Complaint at 6 (D.I. 1). By leveraging computational techniques that can rely on natural stability rather than artificially induced conditions, the claimed invention represents a transformative advancement in coronary physiology, addressing the shortcomings of FFR and paving the way for a more accessible, reliable, and patient-friendly diagnostic technique for coronary stenoses. '463 Patent, 1:41–58, 12:59–13:15; D.I. 1, ¶¶ 29–32.

III. AGREED UPON CONSTRUCTION

The parties agree on the construction for the following term and request that the Court adopt it. *See* D.I. 41, 2.

Term for construction	**Agreed-upon construction**
a cardiac cycle	"at least one cardiac cycle"

IV. DISPUTED CLAIM CONSTRUCTIONS

A. "calculate a pressure ratio" / "calculate a pressure ratio for a diagnostic window of a cardiac cycle"

Patent Claim Term/Phrase	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"calculate a pressure ratio" (Claims 1, 26) "calculate a pressure ratio for a diagnostic window of a cardiac cycle" (Claim 11)	No construction required. Alternatively: "calculate a ratio of pressure measurements" (Claims 1, 26) "calculate a ratio of pressure measurements for a diagnostic window of a cardiac cycle" (Claim 11)	"calculate a pressure ratio for a diagnostic window of only one cardiac cycle" (Claims 1, 11, and 26)

1. Plaintiffs' Opening Position

Defendants' proposed claim constructions should be rejected by the Court because they reflect unsupported and arbitrary narrowing to support their non-infringement positions.

a. No construction is required because the claim language intrinsically construes the terms identified by Defendants.

The plain language of the claims unambiguously describes the way in which "a pressure ratio," is "calculate[d]," giving the term metes and bounds for how the calculation is performed. Where a term is expressly construed within the claims

themselves, as is the case here, further construction is not only unnecessary but risks distorting the claim's plain meaning. *See SecurityPoint Holdings, Inc. v. United States*, 111 Fed. Cl. 1, 8 (2013) ("[A] court need not construe a term if its plain and ordinary meaning is clear and unambiguous in the language of the claim itself.") (citing *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997)); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002) ("The claim language defines the bounds of claim scope.").

Claims 1, 26 and 11 unambiguously state "the pressure ratio is calculated **as an average of the [plurality of / received] distal pressure measurements obtained during the diagnostic window divided by an average of the [plurality of / received] proximal pressure measurements obtained during the diagnostic window."** '463 Patent, Cls. 1, 11, 26 (emphasis added). Claim 1 as a whole, for example, recites the following elements:

> **calculate a pressure ratio** based on a plurality of distal pressure measurements obtained during the diagnostic window and a plurality of proximal pressure measurements obtained during the diagnostic window … wherein **the pressure ratio is calculated as an average of the plurality of distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window.**

See id. (emphasis added). There is no ambiguity, and thus, no need to further construe the term. *See U.S. Surgical Corp.*, 103 F.3d at 1568 ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when

necessary to explain what the patentee covered by the claims, for use in the determination of infringement."). *Aventis Pharms. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363 (Fed. Cir. 2013) ("Courts are required therefore to 'look to the words of the claims themselves … to define the scope of the patented invention.'") (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005)).

b. Not only is Defendants' proposed construction unnecessary, it introduces ambiguity and is unsupported.

Defendants' construction improperly rewrites the claims by injecting a single-cardiac cycle limitation that is neither supported by the intrinsic record nor consistent with well-established principles of claim construction and only introduces ambiguity where none exists by clashing with the agreed-upon construction for "a cardiac cycle."

i. Defendants' construction is inconsistent with the agreed-upon construction for "a cardiac cycle."

Defendants' proposed construction of "calculate a pressure ratio" contradicts the parties' agreement on the construction of "a cardiac cycle." D.I. 41, 2. Despite agreeing that "a cardiac cycle" means "at least one cardiac cycle," Defendants now seek to re-write the claims to exclude multi-cycle calculations from the "calculate" step—introducing unnecessary ambiguity. According to controlling case law and the parties' stipulation, the term "a" must consistently be construed as "one or more."

Id.; *see, e.g.*, *Finjan LLC v. SonicWall, Inc.*, 84 F.4th 963 (Fed. Cir. 2023) (holding that "a" means "one or more").

For example, the version of this term in dispute for claim 11 explicitly contains the term "a cardiac cycle," yet Defendants outright ignore the Parties' agreed-upon construction for that term and replace the term "a cardiac cycle" with "only one cardiac cycle." *See Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001) ("[A] claim term should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent"). The parties' **agreed** and **proposed** constructions would effectively read as follows for claim 11 (with the agreed-upon language for "a cardiac cycle" crossed out by Defendants):

> **Original language:** calculate a pressure ratio for a diagnostic window of **a cardiac cycle**.
>
> **Plaintiffs:** calculate a ratio of pressure measurements for a diagnostic window of at least one cardiac cycle of the patient.
>
> **Defendants:** calculate a pressure ratio for a diagnostic window of ~~at least one cardiac cycle~~ only one cardiac cycle of the patient.

Id. Defendants' proposed construction also seeks to break the antecedent basis that links key limitations together in the claims. For example, claim 11 recites "calculate a pressure ratio for **a diagnostic window** of **a cardiac cycle**…wherein **the pressure ratio** is calculated as an average of…pressure measurements obtained during **the diagnostic window**." *Id.* (emphasis added). Because the "diagnostic window" is of

"a cardiac cycle"—which as stipulated by the parties, means "at least one cardiac cycle"—it necessarily follows that the calculations occurring within "the diagnostic window" must also cover "at least one cardiac cycle,"—yet Defendants insist otherwise. D.I. 41, 2. This type of inconsistency is precisely what claim construction principles seek to avoid. *3rd Eye Surveillance, LLC v. United States*, 140 Fed. Cl. 39, 70 (2018) ("[C]ourts should avoid claim constructions that render terms as surplusage."); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1324 (Fed. Cir. 2001) ("[A] construction that flies in the face of the express language of the claim is not preferred.").

Defendants' conflicting positions are an apparent effort to manufacture noninfringement positions; presumably because Defendants intend to try to distinguish pressure ratios across multiple cardiac cycles. *See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1326 (Fed. Cir. 2006) ("[A] trial court should certainly not prejudge the ultimate infringement analysis by construing claims with an aim to include or exclude an accused product or process").

ii. Defendants' construction unjustifiably narrows the scope of the claims.

Claims 1, 11, and 26 impose no restriction on the number of cardiac cycles over which pressure ratio calculations must be performed and should therefore be afforded their full scope. Courts have long recognized than an applicant is entitled to the full scope of its claim language absent any clear disavowal or contrary

definitions, which is not present here. *See Aug. Tech. Corp. v. Camtek*, *Ltd*., 655 F.3d 1278, 1286 (Fed. Cir. 2011) ("Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.") (quoting *Home Diagnostics*, *Inc. v. LifeScan*, *Inc*., 381 F.3d 1352, 1358 (Fed. Cir. 2004)).

iii. Defendants' construction is inconsistent with dependent claims that require "the pressure ratio" to be calculated across a "plurality of cardiac cycles."

The doctrine of claim differentiation further undermines Defendants' proposed construction. Dependent claims 20 and 21 and dependent claims 28 and 29, which depend from claims 11 and 26 respectively, explicitly recite that the system is configured to calculate the pressure ratio for the "plurality of cardiac cycles." For example, dependent claims 20 and 21 recite:

20. The system of claim 11, wherein the processing unit is further configured to:

calculate ***the pressure ratio*** for the diagnostic window *of each of a plurality of cardiac cycles*.

21. The system of claim 20, wherein the processing unit is further configured to:

calculate an average of *the calculated pressure ratios for the plurality of cardiac cycles* of the patient.

'463 Patent, Cls. 20, 21 (emphases added). Because dependent claims are presumed be narrower than their corresponding independent claims, it follows that independent claims 11 and 26 cannot themselves be limited to only a *single* cardiac cycle because the narrower dependent claims expressly recite using multiple cardiac cycles. *See AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) ("Under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend."); *Phillips*, 415 F.3d at 1303, 1314 ("Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term.") (citing *Vitronics Corp. v. Conceptronic*, *Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

iv. Defendants' construction improperly excludes multiple embodiments from the specification without explanation or reason.

The specification further confirms that the claimed invention is not limited to performing calculations over a single cardiac cycle. *Markman v. Westview Instruments*, *Inc*., 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) ("Claims must be read in view of the specification."). Nowhere in the intrinsic record does the '463 Patent require that the pressure ratio be calculated over only one cardiac cycle as Defendants argue. On the contrary, not only does the '463 Patent extensively describe pressure ratio calculations being averaged across multiple cardiac cycles, but it even describes that approach as a way to improve accuracy.

'463 Patent, 2:36–43, 24:43–47, 27:25–32, 29:4–5, 29:67–30:4, 30:15–32, 31:8–13 ("In other instances, the pressure ratio calculations are performed for multiple cardiac cycles. In that regard, accuracy of the pressure ratio can be improved by performing the pressure ratio calculations over multiple cardiac cycles and averaging the values and/or using an analysis technique to identify one or more of the calculated values that is believed to be most and/or least accurate."). While the claimed invention is certainly capable of performing calculations after just one cardiac cycle, nothing in the intrinsic record requires that it must be limited to only one cycle and any attempt by Defendants to import such a restriction is improper. *Id.*, 27:23–25 ("The pressure ratio calculations of the present disclosure are performed for a single cardiac cycle, *in some instances*.") (emphasis added). *Vitronics Corp.*, 90 F.3d at 1583 (stating that interpretation of patent so that preferred embodiment falls outside of patent claim "is rarely, if ever, correct.").

For these reasons, Defendants' construction should be rejected.

2. Defendants' Answering Position

The parties agree the standalone term "a cardiac cycle" refers to "at least one cardiac cycle." *See* Section III, *supra*. Indeed, courts have recognized that the word "a" means one or more unless there is an exception to depart from that customary meaning based on the claim language and intrinsic record. *See, e.g.*, *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342-43 (Fed. Cir. 2008) ("An

exception to the general rule that 'a' . . . means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule"). An exception to depart exists here.

Claims are construed "as written, not as the patentees wish they had written [them]." *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1345 (Fed. Cir. 2009). The claim language itself—as clarified by the dependent claims—indicates that the calculation of the pressure ratio as recited in the independent claims is done for only one cardiac cycle. The dependent claims (e.g., claim 20) recite the *additional* limitation that the pressure ratio is calculated for "each a plurality of cardiac cycles."

This understanding is supported by the specification that describes both embodiments: a single-cycle calculation and a calculation across a plurality of cycles. Moreover, the prosecution history reveals patentee's intent to limit the scope of the independent claim as the patentee amended independent claim 11 to *remove* the reference to calculating a pressure ratio for a plurality of cardiac cycles, choosing instead to include the *additional element* in a dependent claim. Ex. A, Prosecution History of the '463 Patent, Office Action Response (Dec. 19, 2017) at 15 (claim 10).

Although Defendants agree that "a cardiac cycle," by itself, could refer to one or more cycles, the intrinsic record demonstrates that the terms "calculate a pressure ratio for a diagnostic window of a cardiac cycle" and "calculate a pressure ratio" refer to a calculation for *only* one cardiac cycle.

a. The claims themselves limit the calculation of a pressure ratio to only one cardiac cycle.

To discern the meaning of these claim terms, look no further than the claims. Independent claim 11 recites "calculat[ing] a pressure ratio for a diagnostic window of ***a cardiac cycle***". '463 Patent, cl. 11 (emphasis added). Standing alone, the reference to "a cardiac cycle" may be interpreted as at least one cardiac cycle. *See Convolve, Inc. v. Compaq Comp. Corp.*, 812 F.3d 1313 (Fed. Cir. 2016). Claims, however, must be read within the context of surrounding claims, including dependent claims. *Phillips*, 415 F.3d at 1314-15. For example, dependent claims 20 and 21, which depend from independent claim 11, recite:

> 20. The system of claim 11, wherein the processing unit is ***further configured to:***
> ***calculate the pressure ratio for the diagnostic window of each of a plurality of cardiac cycles.***
>
> 21. The system *of claim 20*, wherein the processing unit is ***further configured to***:
> calculate an average of the ***calculated pressure ratios for the plurality of cardiac cycles*** of the patient.

'463 Patent, cls. 20-21 (emphasis added); *see also* cls. 28-29 (depending from independent claim 26 and reciting same). The patentee's chosen language is telling. Here, patentee added dependent limitations reciting a system with the same capabilities as independent claims 11 and 26 but which are "***further configured***" to calculate the pressure ratio for a plurality of cardiac cycles. In other words, the addition of the calculation for a plurality of cardiac cycles necessarily requires the

calculation in the independent claims to be limited to only one cardiac cycle. Indeed, as the Federal Circuit has noted "[i]nventors are masters of their claims, and the words they use to describe and claim their invention are decisive and binding." *Bio-Rad Labs., Inc. v. Int'l Trade Comm'n*, 998 F.3d 1320, 1331 (Fed. Cir. 2021).

When a limitation—here, the further configuring to calculate pressure ratio for a plurality of cardiac cycles—appears for the first time in a dependent claim, there is a presumption that the limitation is not present in the independent claim. *See, e.g.*, *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302-03 (Fed. Cir. 2003) (holding this presumption "is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim"); *Phillips*, 415 F.3d at 1314-15 ("the presence of a dependent claim ***that adds a particular limitation*** gives rise to a presumption that the limitation in question is not present in the independent claim") (emphasis added); *Invitae Corp. v. Natera Inc.*, No. 21-669-GBW, 2022 WL 10465138, at *2 (D. Del. Oct. 18, 2022) (same). "Claim differentiation . . . is clearly applicable when there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims." *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001).

Plaintiffs' attempt to subsume the added limitations of claims 20 and 21 into the independent claims should be rejected. If the independent claims intended to

recite a calculation across a plurality of cardiac cycles, then dependent claims 20, 21, 28, and 29 would have no distinct meaning. *See Ortho-McNeil Pharm. v. Mylan Lab'ys, Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) ("[T]his court strives to reach a claim construction that does not render claim language in dependent claims meaningless."). Had patentee intended to provide a narrowing limitation, as opposed to an additional element, patentee could have used the "wherein" clause as seen throughout the other dependent claims. *See, e.g.*, '463 Patent, cls. 2-7, 10, 14-19, 22-25, 27-34, 36-54. Utilizing a "wherein" clause gives limiting effect to an independent claim. *See Griffin v. Bertina*, 285 F.3d 1029, 1033-34 (Fed. Cir. 2002). Patentee's decision to, instead, use the transitional phrase "further configured to" for the relevant dependent claims must be given due weight. *See CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) ("In the absence of any evidence to the contrary, we must presume that the use of these different terms in the claims connotes different meanings.").

Accordingly, the plain language of the claims, alone, indicates that the calculation of a pressure ratio, as that term appears in the independent claims, is only done for one cardiac cycle.

b. Defendants' proposed construction is consistent with the specification.

Construing the independent claim terms reciting a calculated pressure ratio as only applying to one cardiac cycle is consistent with the '463 Patent specification.

The specification describes the calculation of a pressure ratio for only one cardiac cycle and for a plurality of cardiac cycles:

> With the proximal and distal pressure measurements aligned, the pressure ratio for the diagnostic window 506 is calculated. In some instances, the pressure ratio is calculated using average values for the proximal and distal pressure measurements across the diagnostic window. ***The pressure ratio calculations of the present disclosure are performed for a single cardiac cycle, in some instances. In other instances, the pressure ratio calculations are performed for multiple cardiac cycles.*** In that regard, accuracy of the pressure ratio can be improved by performing the pressure ratio calculations over multiple cardiac cycles and averaging the values and/or using an analysis technique to identify one or more of the calculated values that is believed to be most and/or least accurate.

'463 Patent, 27:19-32 (emphasis added). Accordingly, the independent claims (e.g., claim 11) are consistent with the disclosed embodiment that "pressure ratio calculations . . . are performed for a single cardiac cycle." *Id.* at 27:23-25; *see also id.* at 31:4-8 ("Because pressure ratio can be calculated based on a single cardiac cycle in accordance with the present disclosure . . . ."). And the dependent claims (*e.g.*, claim 20) are consistent with the disclosed embodiment that "pressure ratio calculations are performed for multiple cardiac cycles." *Id.* at 27:25-27; *see also id.* at 19:18-23. There is no requirement that an independent claim cover every embodiment raised in the specification, especially where the claim language instructs otherwise. *See Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010) ("It is not necessary that each claim read on every embodiment"); *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008)

("Our precedent is replete with examples of subject matter that is included in the specification, but is not claimed."); *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008); *see also PSN Ill., LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1166 (Fed. Cir. 2008) ("courts must recognize that disclosed embodiments may be within the scope of other allowed but unasserted claims").

Thus, the patent specification supports Defendants' proposed construction and the claims, when read as a whole, include embodiments disclosed in the '463 Patent.

c. Patentee's amendments during prosecution reinforce that the calculation recited in the independent claims is performed for only one cardiac cycle.

The prosecution history of the '463 Patent "provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. In fact, the prosecution history may demonstrate "whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* That is precisely what happened during prosecution of the '463 Patent.

Patentee originally drafted independent claim 11 to recite: "calculat[ing], for a diagnostic window of each of the plurality of cardiac cycles of the patient, a pressure ratio". Ex. A, Office Action Response (Sept. 13, 2016) at 4 (claim 10). In response to a rejection, patentee amended that claim to narrow its scope to only cover a single cardiac cycle:

> calculate, for a diagnostic window of ~~**each of the plurality of cardiac cycles**~~ **a cardiac cycle** of the patient, a pressure ratio of ~~**an average of**~~ the received distal pressure

Id. at Office Action Response (Dec. 19, 2017) at 15 (claim 10). In the same amendment, patentee added new dependent claims which recited the "plurality of cardiac cycles" that were originally present in the independent claim. *See, e.g.*, *id.* at claim 21 ("The system of claim 10, wherein the processing unit is further configured to: calculate the pressure ratio for the diagnostic window of each of a plurality of cardiac cycles"). Thus, during prosecution, patentee understood the independent claims to recite a calculated pressure ratio for only one cardiac cycle, while the dependent claims extended that calculation to a plurality of cardiac cycles.

The examiner shared patentee's understanding. In the Notice of Allowance, the examiner distinguished the allowed (now issued) claims over the prior art noting the prior art's "pressure ratios are calculated differently and ***are not compatible with averaging the measurements within in a single window to find the averaged ratio over that window.***" *Id.* at Notice of Allowance (Oct. 5, 2020) at 2 (emphasis added); *see also id.* at Office Action (June 25, 2020) at 15. Thus, the prosecution history confirms what is made clear in the claims and specification: the "calculated pressure ratio" in the independent claims is calculated based on only one cardiac cycle, whereas the dependent claims extend that calculation to a plurality of cardiac cycles.

d. The intrinsic record provides an exception to depart from the general rule that "a" means one or more as it is applied to "calculate a pressure ratio" claim terms.

While the article "a" usually is interpreted to mean "one or more," courts have found that the claim language, specification, and prosecution history may necessitate a departure from that rule. *See Baldwin Graphic*, 512 F.3d at 1342-43; *Harari v. Lee*, 656 F.3d 1331, 1341 (Fed. Cir. 2011) (holding that the "plain language of the claim clearly indicates" that the "a" referenced in the claim language refers to "only a single bit line" as opposed to a plurality of bit lines). As explained above, the '463 Patent claim language, specification, and prosecution history reinforce Defendants' proposed construction that the "calculate a pressure ratio" terms as they appear in the independent claims be limited to the calculation during a single cardiac cycle.

Unlike claims 11 and 26, which include dependent claims adding that the system is "further configured" to calculate a pressure ratio for a plurality of cardiac cycles, claim 1 does not include mirroring dependent limitations. That said, the term "calculate a pressure ratio" in claim 1 should be interpreted consistently with those phrases in claims 11 and 26. *See Phillips*, 415 F.3d at 1314 ("claim terms are normally used consistently throughout the patent"). "[T]he principle that the same phrase in different claims of the same patent should have the same meaning is a strong one, overcome only if it is clear that the same phrase has different meanings

in different claims." *In re Varma*, 816 F.3d 1352, 1364 (Fed. Cir. 2016). There is no clear evidence here that patentee intended the calculated pressure ratio in claim 1 to extend across multiple cardiac cycles. *Cf. Convolve, Inc.*, 812 F.3d 1313 (interpreting "a processor" differently across claims where the claims recited structural differences indicating a difference between a singular or plural processors).

The patentee's chosen claim language, description in the specification, and amendments and comments during prosecution indicate the "calculate a pressure ratio" terms are intended to be done for only one cardiac cycle as recited in independent claims 1, 11, and 26.

Defendants respectfully request the Court adopt their proposed constructions for these terms.

3. Plaintiffs' Reply Position

Defendants admit that clear evidence is required to depart from the strong presumption that "a" means "at least one," but Defendants cannot point to a single instance in the claim language, specification, or prosecution history that shows this departure. *See* Section IV.A.2, *supra*. Instead, Defendants attempt to obscure the facts by taking citations to the '463 Patent, prosecution history, and Federal Circuit precedent completely out of context. Even further, Defendants attempt to improperly shift their own burden to establish disclaimer onto the patentee—asserting that "[t]here is no clear evidence [] that patentee intended the calculated pressure ratio in

claim 1 to extend across multiple cardiac cycles." *See* Section IV.A.2.d, *supra*; *Intell. Ventures I LLC v. T-Mobile USA, Inc.*, 902 F.3d 1372, 1378-79 (Fed. Cir. 2018) ("Disavowal is an 'exacting' standard under which it must be established that the patentee 'demonstrate[d] an intent to deviate from the ordinary and accustomed meaning of a claim term' through 'expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.'" (citing *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009))).

a. Defendants' proposed construction is not supported by the dependent claims because they narrow the scope covered in the independent claims, not add subsequent operations.

Under the doctrine of claim differentiation, the presence of multi-cycle calculations in the dependent claims gives rise to the presumption that the independent claims are inclusive of single-cycle and multi-cycle calculations. *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir. 2022) ("By definition, an independent claim is broader than a claim that depends from it, so if a dependent claim reads on a particular embodiment of the claimed invention, the corresponding independent claim must cover that embodiment as well.") Defendants insist the opposite is true.

Defendants first contend that the use of "further configured to" in the dependent claim preambles implies that the recited steps are entirely new and subsequent—reasoning that, otherwise, there would be no distinction from the

independent claims. Sections IV.A.2.a, *supra*, IV.B.2.a, *infra*. Second, they assert that any limitation "appear[ing] for the first time" in a dependent claim, is *presumed to be excluded* from the independent claim. *Id*. Defendants' position is not only unsupported by precedent—it is the exact opposite of prevailing Federal Circuit law on this point.

i. Federal Circuit precedent, including every case cited by Defendants, confirms that the independent claims include within their scope single and multi-cycle calculations.

Defendants fail to cite a single case where an independent claim was construed to exclude scope described in claims that depend from it. Instead, their own cases support Plaintiffs' position: a patent's dependent claims further *limit* (not expand) the scope of the independent claims.

Courts have consistently recognized that dependent claims can disclose a narrower subset of implementations covered in the independent claims without creating conflict or rendering either claim meaningless. But Defendants argue the opposite here, contending that the dependent claims create new scope rather than narrowing the scope covered by the independent claims. *See* Section IV.A.2.a, *supra*. In an attempt to support that interpretation, Defendants cite a line of cases that never even considered that view, much less adopted it. In every case cited by Defendants, the court refused to *read in* limitations from the dependent claims into the independent claims because the independent claims were presumably broader and

doing so would render the dependent claims superfluous. Here, neither Defendants nor Plaintiffs are seeking to narrow the independent claims to the multi-cycle calculations recited in the dependent claims. Instead, Defendants are doing just the opposite by seeking to limit the independent claims to single-cycle calculations, thereby excluding the scope of the dependent claims. *See SunRace Roots Enter. Co.*, 336 F.3d 1298; *Invitae Corp.*, No. 21-669-GBW, 2022 WL 10465138; *Wenger Mfg., Inc.*, 239 F.3d 1225; *Ortho-McNeil Pharm.*, 520 F.3d 1358; *Griffin*, 285 F.3d at 1033-34.

For example, in the case cited by Defendants, *Liebel-Flarsheim Co. v. Medrad, Inc.*, because the dependent claim "add[ed] a pressure jacket limitation," the court found the independent claims could include, but did not "require the presence of a pressure jacket." 358 F.3d 898, 910 (Fed. Cir. 2004). Similarly, here, because the dependent claims "add" multi-cycle calculations, the independent claims include, but do not "require," multi-cycle calculations, thus the scope of the claims includes both single and multi-cycle calculations.

Defendants' construction also leads to internal contradictions. If, as Defendants contend, the phrase "the calculated pressure ratio" in the independent claims *cannot* undergo multi-cycle calculations, but the exact same phrase in the dependent claims *can*, their interpretation violates the bedrock principle of claim construction that "the same phrase in different claims of the same patent should have

the same meaning." *Intelligent Automation Design, LLC v. Zimmer Biomet CMF & Thoracic, LLC*, 799 F. App'x 847, 850 (Fed. Cir. 2020); *see HowLink Glob. LLC v. Network Commc'ns Int'l Corp.*, 561 F. App'x 898, 903 (Fed. Cir. 2014)) (claim terms "[b]ased on [an] antecedent basis relationship … carry the same meaning throughout the claims"). For example, dependent claims 20, 21, and 22, all pertaining to multi-cycle calculations, each recite "the pressure ratio" or "the calculated pressure ratio," as recited in independent claim 11. *See* '463 Patent, cls. 11, 20-22. They do not, for example, recite a second pressure ratio, one that can undergo additional calculations, or processing steps.

In addition, the phrase "further configured to," as used in the preamble in *some* of the dependent claims, does not imply a new, otherwise unclaimed operation. Rather, it simply adds specificity as to how an existing operation is carried out. In *Koninklijke KPN N.V. v. Gemalto M2M GmbH*, the Federal Circuit directly addressed this issue, finding that a dependent claim "further configured to" apply a specific technique merely "recites a specific implementation … that improves the ability of [] [the] system[]"—not an additional operation. 942 F.3d 1143, 1150 (Fed. Cir. 2019). The court further explained that one of these dependent claims "further recites *how*" a limitation recited in the independent claim is carried out. *Id*. at 1148 (emphasis added).

Defendants also attempt to distinguish the use of "wherein" versus "further configured to" to draw a line between limitations that supposedly recite new steps versus those that do not. *See* Section IV.A.2.a, *supra*. The dependent claims at issue use both phrases together—*wherein* the processing unit is *further configured to* ..."—eliminating any meaningful distinction. *See* '463 Patent, cls. 20, 21, 23, 28, 29, 31.

b. Defendants concede that the specification discloses both single and multi-cycle pressure ratio calculations.

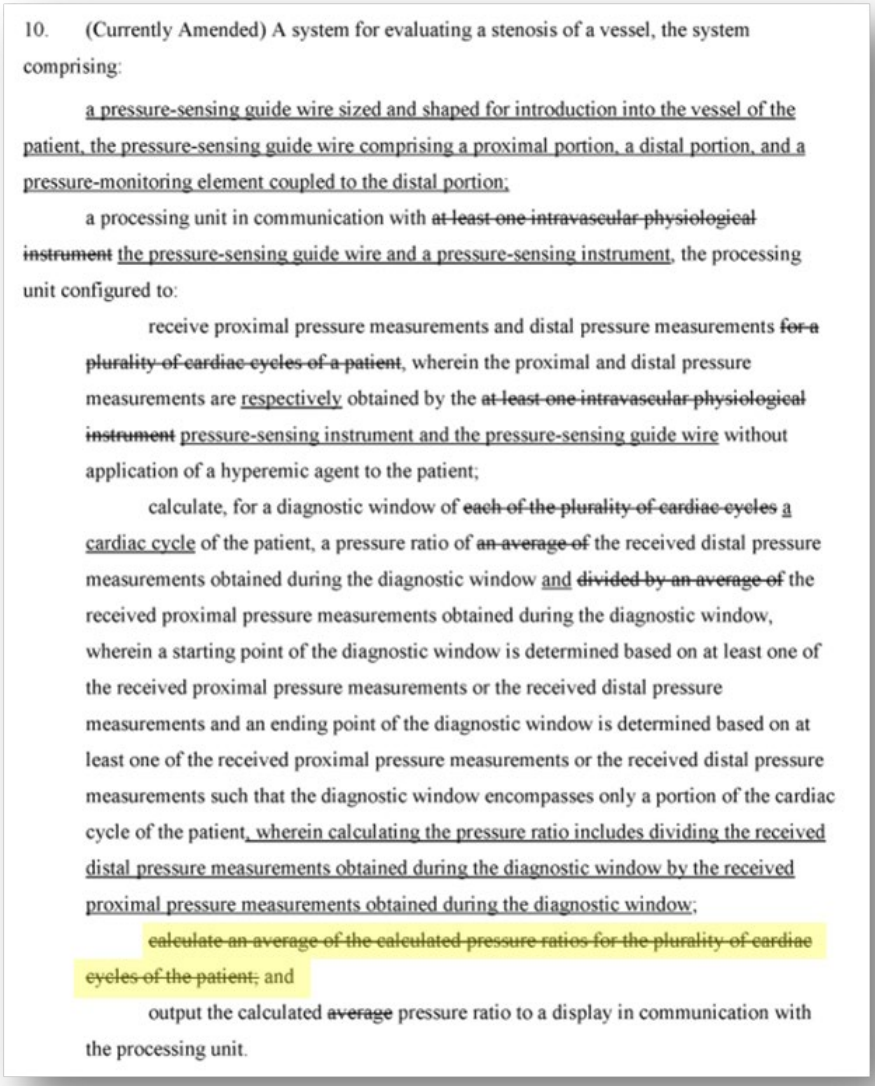
Defendants' construction is not only inconsistent with the plain language of the claims, but also unsupported by the specification. It is undisputed that the '463 patent discloses numerous embodiments covering multi-cycle calculations. Yet, under Defendants' interpretation, multi-cycle calculations are only permitted if the system first performs single-cycle calculations. There is no such requirement disclosed in the specification. *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 792 (Fed. Cir. 2010) ("A construing court's reliance on the specification must not go so far as to import limitations into the claims from examples or embodiments appearing only in a patent's written description unless the specification makes clear that the patentee intends for the claims and the embodiments in the specification to be strictly coextensive.") (internal quotation marks omitted).

As Defendants acknowledge, the '463 patent discloses that the claimed system permits the operator to choose a specific mode (single- or multi-cycle mode) depending on their desired purpose. *See* Section IV.A.2.b, *supra*. Single-cycle mode serves to generate a live ratio as the guidewire is moving through the vessel, whereas multi-cycle mode generates a ratio in a "discrete location" in the vessel. *See* '463 Patent, 31:4-19. Among numerous additional disclosures, the specification also discloses techniques for selecting a diagnostic window based on "overlapping areas common to the *plurality of cardiac cycles*," which are then used to "calculat[e] an average" pressure ratio—reaffirming that the system can perform all its operations, beginning with receiving pressure measurements up to calculating the pressure ratio, across multiple cardiac cycles. *Id*., 19:10-27. Given the breadth of disclosure affirming multi-cycle calculations are covered by the independent claims, Defendants' contrary argument should be rejected.

c. The prosecution history does not evidence any disclaimer of multi-cycle pressure ratio calculations.

Nor do Defendants' prosecution history arguments bear their clear evidence burden. *Intell. Ventures I*, 902 F.3d at 1378-79 (holding that for prosecution history estoppel, a party must demonstrate clear and unequivocal disclaimer made by the patentee's statements). Defendants focus on the prosecution amendment to claim 10, wherein the "plurality of cardiac cycles" language was removed from the independent claim and moved instead to a dependent claim. *See* Section IV.A.2.c,

supra. Once again, Defendants get it backwards: by removing a limitation, a claim gets broader—not narrower. *In re Clement*, 131 F.3d 1464, 1468 (Fed. Cir. 1997) (A "claim that deletes a limitation or element from the patent claims is broader in that limitation's aspect."). By amending claim 10, Applicants broadened the claim to include both *single*- and *multi*-cycle calculations, in line with claim 1, while still preserving multi-cycle coverage through the addition of the dependent claim—along with 38 other new claims. *See* Ex. B, Office Action Response (Dec. 19, 2017). Defendants also omit that claim 1, as filed, *already* recited the term "a cardiac cycle,"—which they concede means by default "one or more cardiac cycles"—and that this language never changed. *See* Ex. C, Claims (Mar. 25, 2016); '463 Patent, cl. 1.



10. (Currently Amended) A system for evaluating a stenosis of a vessel, the system comprising:

a pressure-sensing guide wire sized and shaped for introduction into the vessel of the patient, the pressure-sensing guide wire comprising a proximal portion, a distal portion, and a pressure-monitoring element coupled to the distal portion;

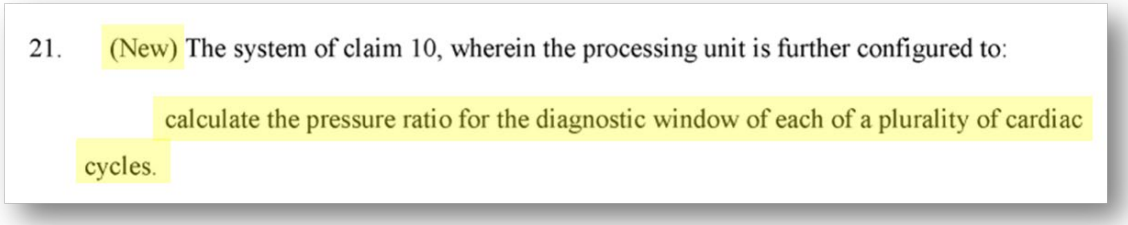
a processing unit in communication with ~~at least one intravascular physiological instrument~~ the pressure-sensing guide wire and a pressure-sensing instrument, the processing unit configured to:

receive proximal pressure measurements and distal pressure measurements ~~for a plurality of cardiac cycles of a patient~~, wherein the proximal and distal pressure measurements are respectively obtained by the ~~at least one intravascular physiological instrument~~ pressure-sensing instrument and the pressure-sensing guide wire without application of a hyperemic agent to the patient;

calculate, for a diagnostic window of ~~each of the plurality of cardiac cycles~~ a cardiac cycle of the patient, a pressure ratio of ~~an average of~~ the received distal pressure measurements obtained during the diagnostic window and ~~divided by an average of~~ the received proximal pressure measurements obtained during the diagnostic window, wherein a starting point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements and an ending point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements such that the diagnostic window encompasses only a portion of the cardiac cycle of the patient, wherein calculating the pressure ratio includes dividing the received distal pressure measurements obtained during the diagnostic window by the received proximal pressure measurements obtained during the diagnostic window;

~~calculate an average of the calculated pressure ratios for the plurality of cardiac cycles of the patient;~~ and

output the calculated ~~average~~ pressure ratio to a display in communication with the processing unit.



21. (New) The system of claim 10, wherein the processing unit is further configured to:

calculate the pressure ratio for the diagnostic window of each of a plurality of cardiac cycles.

Ex. B, Office Action Response (Dec. 19, 2017) (claims 10 and 21). Defendants also misstate the purpose behind these amendments, implying they were made to

distinguish over prior art. *See* Section IV.A.2.c, *supra*. That is incorrect. Not only did the Examiner *never* raise any prior art rejections based on the number of cardiac cycles, but there was never even any discussion of the number of cycles disclosed in the prior art whatsoever. *See* Ex. D, Office Action (Sept. 19, 2017). Applicants made these amendments in response to the Examiner issuing *only* § 101 rejections—not to overcome prior art. *See id.*

Defendants' claim that the Examiner's statements confirm the independent claims perform single-cycle calculations is incorrect. To support their view, Defendants point to where the Examiner used the word "single" without including the complete context. *See* Section IV.A.2.c, *supra*. The Examiner's full statement reads: "*as discussed in prior Office Actions*, Shalman's pressure ratios are [1] calculated differently and [2] are not compatible with averaging the measurements **within [] a single window** to find the averaged ratio **over that window**." Ex. E, Notice of Allowance (Oct. 5, 2020) at 2 (emphases added). The Examiner thus distinguished Shalman in two ways: first, noting that Shalman disclosed different calculations, and secondly, noting that it was not compatible with using a single diagnostic ***window*** *within a given cardiac cycle*. *See id.*

As stated by the Examiner, this was previously discussed in prior office actions where the Examiner repeatedly acknowledged that Shalman did not disclose the claimed *diagnostic window*. Ex. F, Office Action Response (Sept. 13, 2016) at 6

("[During the August 10, 2016 Examiner Interview], it was agreed that pending claims distinguished over the cited references" because they "do not disclose or suggest using a **diagnostic window within a cardiac cycle** of a patient to calculate a pressure ratio as recited by the claims.") (emphasis added); *see also* Ex. G, Office Action (Jan. 11, 2017) at 4; Ex. D, Office Action (Sept. 19, 2017) at 11. In other words, the Examiner stated that pressure measurements are taken from one diagnostic window within a cardiac cycle, but this process may be repeated across a "plurality of cardiac cycles" to improve accuracy. *See* '463 Patent, 27:25-32. Contrary to Defendants' argument, this distinction made during prosecution was based on using the claimed window within a cardiac cycle, not the number of cycles. In short, nothing in the prosecution history provides clear evidence that the patentee disclaimed multi-cycle pressure ratio calculations from the independent claims.

4. Defendants' Sur-Reply Position

Plaintiffs' proposed construction is an attempt to rewrite the claim language in the manner Plaintiffs wish they had been drafted. While Plaintiffs may wish for the independent claims to cover a pressure ratio calculated across a plurality of cardiac cycles, the intrinsic record makes clear that the independent claims require a system that "calculate[s] a pressure ratio" for one cardiac cycle, regardless of whether the claim is broad enough to *also* separately cover calculating a pressure ratio for multiple cardiac cycles. The dependent claims (*e.g.*, claim 20), consistent

with specification, recite the *additional* limitation that the pressure ratio is calculated for a plurality of cardiac cycles. And the prosecution history reinforces this meaning, indicating patentee *chose* to limit the independent clams as requiring only a calculation of a pressure ratio for a diagnostic window of *one* cardiac cycle—removing the plurality of cardiac cycles from the independent claims—moving that recitation into the dependent claims. *See* Ex. A, Office Action Response (Dec. 19, 2017) at 15 (claim 10).

a. The dependent claims are limiting while providing an additional requirement that the pressure ratio is calculated across multiple cardiac cycles.

A dependent claim that adds a limitation to an independent claim is, nevertheless, limiting. Here, the dependent claims that recite the additional limitation that the claimed system is configured to calculate a pressure ratio for a plurality of cardiac cycles accordingly underscores the narrowness of the respective independent claims that require the calculation for only one cardiac cycle. *See* '463 Patent, cls. 20-21, 28-29. Contrary to Plaintiffs' position, the independent claims are within the "scope" of the dependent claims, for example, by covering a system that calculates a pressure ratio for one cardiac cycle *and* calculates a pressure ratio across a plurality of cardiac cycles. *See* Section IV.A.3.a.i, *supra*. The only "meaningful difference" between the independent claims and the relevant dependent claims are the number of cardiac cycles for which the pressure ratio is calculated.

SunRace Roots Enter. Co., 336 F.3d at 1302-03. This leads to the presumption that this limitation is not required by the independent claim. *See id.*; *see also Invitae Corp.*, No. 21-669, 2022 WL 10465138, at *2.

Patentee indicated that the multi-cycle calculation was additional to the single-cycle calculation of the independent claims by reciting a system "***further configured***" to perform the multi-cycle calculation. *See* '463 Patent, cls. 20-21, 28-29 (emphasis added). Despite their contention that Federal Circuit precedent governs the meaning of "further configured," the cases cited by Plaintiffs are misplaced. *See* Section IV.A.3.a.i, *supra*. For example, *Koninklijke KPN N.V. v. Gemalto M2M GmbH* decided validity under 35 U.S.C. § 101 and merely found the "further configured" dependent claim to also include a "non-abstract improvement" over the technological field and a "specific implementation" of the patented invention. 942 F.3d at 1150. The opinion says nothing about claim meaning nor that a "further configured" dependent claim limitation is always subsumed within the recited independent claim. *See generally id.*; *see also Griffin,* 285 F.3d at 1033-34 (cited by Plaintiffs, Section IV.A.3.a.i, *supra*) (explaining that a "wherein" preamble may be limiting or not limiting depending on the facts of the case).

On the other hand, the Patent Office has instructed that certain transitional phrases in dependent claims, such as "further comprising," are used "[w]hen you are ***adding a component***" while other transitional phrases, such as "wherein," are used

when "further describing something that has already been introduced". Ex. P at 24. Importantly, the Patent Office still recognizes that each type of dependent claim—whether adding a limitation or simply elaborating one previously-introduced—remains limiting of an independent claim. *Id.* at 5. If the patentee intended to provide further description of an element previously raised, they could have used the "wherein" clause as seen throughout the other dependent claims.

Plaintiffs' attention to dependent claims 20-21 and 28-29 also using the "wherein" transition is of no import. *See* Section IV.A.3.a.i, *supra*. Those "wherein" clauses are used to describe the processing unit which is "further configured" to calculate the pressure ratio in a manner not-before-described in the independent claims: across a plurality of cardiac cycles. '463 Patent, cls. 20-21, 28-29. The plain language of the claims supports Defendants' proposed construction.

b. The patent specification and prosecution history support Defendants' proposed construction.

As noted previously, Defendants agree that the '463 Patent specification describes an embodiment in which "the pressure ratio calculations are performed for multiple cardiac cycles." *See* Section IV.A.2.b, *supra*; '463 Patent at 27:19-32. The specification also discloses an alternative embodiment wherein "the pressure ratio calculations . . . are performed for a single cardiac cycle." '463 Patent at 27:23-35. The claim language aligns with these disclosed embodiments: (1) the single cardiac cycle pressure ratio calculation is required by the independent claims, and (2) the

multiple cardiac cycle pressure ratio calculations are added and required by the dependent claims. There is no requirement that each independent claim cover each stated embodiment, especially where the claims themselves indicate otherwise. *See, e.g.*, *Baran*, 616 F.3d at 1316; *TIP Sys., LLC*, 529 F.3d at 1373.

c. The prosecution history further supports that the calculation of a pressure ratio in the independent claims is done for one cardiac cycle.

Patentee originally drafted independent claim 11 to cover calculating a pressure ratio for "each of the plurality of cardiac cycles." Ex. A. Office Action Response (Sept. 13, 2016) at 3-4 (claim 10). To place the claims into condition for allowance, patentee removed that limitation from the independent claims, adding it into a new dependent claim instead. *Id.* at Office Action Response (Dec. 19, 2017) at 15 (claim 10); *id.* at claim 21. Plaintiffs' attempt to minimize the impact of this amendment based on the type of examiner rejection (*e.g.*, under 35 U.S.C. § 101 instead of §§ 102 or 103) is unavailing. *See Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 583 (D. Del. 2004) ("The [Federal Circuit] also determined that prosecution history is 'always relevant to claim construction' and that a 'narrowing amendment to satisfy any requirement of the Patent Act may give rise to an estoppel.'") (quoting *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1327 (Fed. Cir. 2003)); *see also Philips*, 415 F.3d at 1317 (claim amendments during

prosecution history "provide[] evidence of how the PTO and the inventor understood the patent").

Similarly unavailing is Plaintiffs' argument that removing this limitation from the independent claim and placing it into a "further configured" dependent claim broadened the independent claim scope. *See* Section IV.A.3.c, *supra*. As discussed in *In re Clement*, cited by Plaintiffs for this proposition, whether removal of a limitation from an independent claim will broaden or narrow that claim depends on the claim language, specific facts, and reason for the amendment. *Id.*; *In re Clement*, 131 F.3d at 1468 (holding for the purposes of a reissue that the removal of a limitation actually broadened the claim); *id.* at 1470 (discussing *Ball Corp. v. U.S.*, 729 F.2d 1429, at 1432-33 (Fed. Cir. 1984) (holding removal of a limitation from "feed means . . ." to "a plurality of feedlines" in fact narrowed the claim)).

The entirety of the intrinsic record makes plain that the claims mean exactly what they say. The calculation of a pressure ratio as recited in the independent claims must be done for one cardiac cycle; whereas the calculation of the pressure ratio across a plurality of cardiac cycles is a limitation added by the dependent claims.

B. "output … the calculated pressure ratio"

Patent Claim Term/Phrase	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
output … the calculated pressure ratio (Claims 1, 11, and 26)	No construction required. Alternatively: "output the calculated ratio of pressure measurements"	"output … the pressure ratio calculated for a diagnostic window of only one cardiac cycle, where the pressure ratio is calculated only as an average of the plurality of distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window without additional calculation"

1. Plaintiffs' Opening Position

a. No construction is required because the claim intrinsically construes the term.

As with the previous term, no construction is necessary for this term because the claim language itself provides a clear and explicit construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) ("The starting point for any claim construction must be the patent claims themselves."). Claims 1, 11, and 26 explicitly construe the pressure ratio that is output to the display. '463 Patent, Cls. 1, 11, 26. Straightforwardly, the "displayed pressure ratio" is the "calculated pressure ratio" in the preceding and following steps and introducing

further definitional language would only result in tautological and superfluous phrasing. For instance, Defendants' proposed claim construction as it compares to Plaintiffs' applied to claims 1 and 26 is illustrated below:

> **Plaintiffs:** output … the calculated ratio of pressure measurements for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patient, wherein the pressure ratio is calculated as an average of the plurality of distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window.
>
> **Defendants:** output … the pressure ratio calculated for a diagnostic window of only one cardiac cycle, where the pressure ratio is calculated only as an average of the plurality of distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window without additional calculation, for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patient, wherein the pressure ratio is calculated as an average of the plurality of distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window.

See id. The repetition introduced by Defendants' proposed construction does not resolve any ambiguity; rather it introduces redundancy and creates a claim construction that is, at best, unhelpful and at worst, nonsensical. *See AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1277 (Fed. Cir. 2011) ("[A court] strive[s], where possible, to avoid nonsensical results in construing claim language.").

b. Defendants' proposed construction is unsupported by the intrinsic record.

In addition to limiting the term "output … the calculated pressure ratio" to "only one cardiac cycle," Defendants' construction restricts the displayed ratio to prohibit "additional calculations." Defendants' proposed construction impermissibly narrows the scope of the claims by excluding disclosed embodiments in an attempt to tailor the claim language to their noninfringement arguments. D.I. 41, 2; *Wilson Sporting Goods Co.*, 442 F.3d 1331 ("The court] forbids biasing the claim construction process to exclude or include specific features of the accused product or process."); *Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1331 (Fed. Cir. 2011) ("[T]he role of a [federal trial judge] in construing claims is not to redefine claim recitations or to read limitations into the claim to obviate factual questions of infringement.").

i. Defendants' construction unjustifiably narrows the scope of the claims.

The "output" term proposed by Defendants for construction imposes no restriction on whether the displayed pressure ratio may include additional calculations. It only requires that "the calculated pressure ratio" be displayed, while other elements of the claims describe the pressure ratio calculation. *See* Section IV.A, *supra*. And while the claims specify the calculation used to determine the pressure ratio, they do not forbid, in the "output" term or elsewhere, additional processing or

refinement of that ratio such as the averaging or normalization described in the '463 patent. *See* Section IV.B.1.b.ii, *infra*. The law does not require patentees to enumerate every possible refinement or processing step within the claim language to be afforded full claim scope. The specification serves to describe the broader scope of the invention. *See On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1339–40 (Fed. Cir. 2006) ("In general, the scope and outer boundary of claims is set by the patentee's description of his invention.") (citing *Phillips*, 415 F.3d at 1313–14). Therefore, the absence of an explicit reference to additional calculations[2] does not imply a limitation prohibiting them. *Ecolab, Inc.*, 569 F.3d at 1345 ("[A] court[] generally may not re-draft claims; [the claims] must [be] construe[d] as written.").

The open claim language in the preamble of the claims further confirms that additional calculations are not excluded. The Federal Circuit has long held that "comprising" in the preamble creates the presumption that the claim is open-ended and permits the inclusion of unrecited elements unless there is clear evidence of contrary intent. *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001) ("'[C]omprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude

[2] As noted below, additional calculations *are* explicitly recited in the claims that depend from—and further narrow—these independent claims.

additional, unrecited elements."). Because the term "comprising" is used in the preamble of claims 1, 11, and 26, and there is no disclaimer or express definition in the record restricting additional calculations, the claims merely require that the ratio *include* this calculation, not that it be the *sole* calculation. '463 Patent, Cls. 1, 11, 26; *see Aug. Tech. Corp*., 655 F.3d at 1278.

ii. Defendants' construction improperly excludes multiple embodiments from the specification.

Nowhere does the specification preclude additional calculations from being performed and reflected in the displayed pressure ratio. In fact, the intrinsic record discloses numerous methods to incorporate additional calculations to refine the accuracy and stability of the pressure ratio calculated, including: (1) normalization to adjust for variations in the baseline pressure, (2) filtration to remove noise and artifacts, (3) temporal alignment methods to synchronize proximal and distal waveforms, (4) derivative-based analysis to identify stable diagnostic windows, (5) standard deviation calculations to filter out irregular cycles, and (6) wave intensity analysis to isolate pressure contributions from different sources. '463 Patent, 25:5–27:32, 28:31–46, 29:28–31:3. To the extent that some embodiments in the specification display a pressure ratio that does not incorporate additional calculations, that is certainly not dispositive of the full scope that should be accorded to the claims. *See Oatey Co. v. IPS Corp*., 514 F.3d 1271, 1276 (Fed.

Cir. 2008) ("We normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification.").

iii. Defendants' construction is inconsistent with the dependent claims, which require additional calculations.

The dependent claims further undermine Defendants' proposed construction as they recite systems which perform additional calculations. For example, claims 30 and 32 (both depending from claim 26) recite:

> 30. The system of claim 29, wherein the processing unit is configured to output the average of the calculated pressure ratios to the display.
>
> 32. The system of claim 31, wherein the processing unit is configured to output the calculated average to the display only when the difference is below a threshold value.

'463 Patent, Cls. 26–32. Therefore, in at least some claimed embodiments, the system necessarily performs additional calculations, including, for example, an additional averaging step and/or comparison operation. Defendants' proposed construction is inconsistent with these dependent claims, which expressly contemplate additional calculations, since dependent claims narrow, rather than broaden, the independent claims from which they depend. *See Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1255 (Fed. Cir. 2010) ("A claim

construction that renders asserted claims facially nonsensical 'cannot be correct.'") (quoting *Schoenhaus v. Genesco, Inc*., 440 F.3d 1354, 1357 (Fed. Cir. 2006)); *AK Steel Corp.*, 344 F.3d at 1234.

2. Defendants' Answering Position

The parties agree "[t]he plain language of the claims unambiguously describes the way in which 'a pressure ratio,' is 'calculate[d],' giving the term metes and bounds for how the calculation is performed." *See* Section IV.A.1.a, *supra*. Claim 1, for example, unambiguously recites:

> "the pressure ratio is calculated as an average of the [plurality of / received] distal pressure measurements obtained during the diagnostic window divided by an average of the [plurality of / received] proximal pressure measurements obtained during the diagnostic window."[3]

'463 Patent, cl. 1; *see also id.* cls. 11, 26 (same); *see* Section IV.A.1.a, *supra*. Indeed, "[c]laims 1, 11, and 26 explicitly construe the pressure ratio that is output to the display." *See* Section IV.B.1.a, *supra*. It is this explicitly defined pressure ratio that is "output" to the display. '463 Patent, cl. 1. Full stop. Despite the parties' mutual understanding, Plaintiffs seek to extend the explicitly recited calculation to encompass any steps, permutations, or additional calculations that could foreseeably be performed. Doing so would fundamentally transform the recited pressure ratio into something it is not.

[3] For convenience, Defendants will refer to this recited pressure calculation as "average Pd / average Pa" in this brief.

Accordingly, construction of this term is required to "clarify and . . . explain what the patentee covered by the claims, for use in the determination of infringement." *U.S. Surgical Corp.*, 103 F.3d at 1568. Moreover, although both parties agree the meaning of the claim is unambiguous, the parties have a "fundamental dispute regarding the scope of [this] claim term." *02 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). This term is, therefore, ripe for construction.

Defendants' proposed construction properly sets the metes and bounds for the calculated pressure ratio that is ultimately output to a display. Defendants' proposed construction aligns with the claim language and specification and is further supported by patentee's arguments and amendments during prosecution.[4] On the other hand, Plaintiffs seek to impermissibly broaden the recited calculation to include steps and other calculations that are not in the claims. The independent claims recite a defined mathematical equation (average Pd / average Pa) and any

[4] Defendants address the portion of their construction relating to the calculated pressure ratio which is calculated *only* as average Pd / average Pa without additional calculation in this Section of their brief. Defendants acknowledge that their proposed construction also ties into the previous claim terms—"calculated pressure ratio" terms—and references that the pressure ratio is calculated for only one cardiac cycle. Defendants refer to Sections IV.A.2 and IV.A.4, *supra* regarding their argument concerning the calculation during one cardiac cycle.

additional calculations would fundamentally alter the recited calculation and the claim itself.

a. The parties agree "the plain language of the claims unambiguously describes the way in which a pressure ratio is calculated."

"Claims 1, 11, and 26 explicitly construe the pressure ratio that is output to the display." *See* Section IV.B.1.a, *supra*. In fact, the claims explicitly state the pressure ratio is "calculated as" average Pd / average Pa. '463 Patent, cls. 1, 11, 26. As the parties agree, "[t]he claim language defines the bounds of claim scope." *Teleflex, Inc.*, 299 F.3d at 1324; *see also* Section IV.A.1.a, *supra*. That scope cannot be extended to cover additional calculations not explicitly included in the claimed mathematical equation. *See In re Application of Richman*, 563 F.2d 1026, 1030 (C.C.P.A. 1977) (finding no difference between claims drafted in "a simple, formula expression of a mathematical relationship" and those drafted "with words which mean the same thing"). To hold otherwise would impermissibly change the claim scope and the claim element—the calculated pressure ratio—itself.

The plain language of the claims reinforces that what is output to a display is average Pd / average Pa. For example, claim 1 recites:

> Calculate ***a pressure ratio*** based on a plurality of distal pressure measurements obtained during the diagnostic window and a plurality of proximal pressure measurements obtained during the diagnostic window; and

> ***Output***, to a display in communication with the processing unit, ***the calculated pressure ratio*** for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patient,
>
> Wherein ***the pressure ratio*** is ***calculated as*** an average of the plurality of distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window.

'463 Patent, cl. 1 (emphasis added); *see also id.*, cls. 11, 26. Accordingly, it is the same pressure ratio, and only this pressure ratio—which the parties agree is defined in the last limitation of claim 1—that is output to the display.

The language patentee chose to include in claim 1 when defining the pressure ratio is also instructive. As shown above, in one limitation claim 1 recites the pressure ratio is "***based on***" distal and proximal pressure measurements taken during the diagnostic window. *Id.*, cl. 1. In the last limitation, which explicitly defines how the calculation is performed, the claim recites the pressure ratio is "***calculated as***" average Pd / average Pa. Unlike the prior term, "based on," which is open-ended, patentee chose to explicitly define the mathematical equation used for the pressure ratio calculation. *See CAE Screenplates*, 224 F.3d at 1317 ("In the absence of any evidence to the contrary, we must presume that the use of these different terms in the claims connotes different meanings."). Lastly, the claims make clear that it is the pressure ratio—calculated as average Pd / average Pa—which is output to a display and not any other calculation. '463 Patent, cls. 1, 11, 26.

Defendants' understanding of the recited pressure ratio is also supported by the dependent claims. Plaintiffs point to dependent claims 30 and 32 which reference an "average" of "the calculated pressure ratios". *See* Section IV.B.1.b.iii, *supra*; '463 Patent, cls. 30, 32. These dependent claims depend from the dependent claims discussed above that include the "further configured" language. Claims 30 and 32 recite *additional* functionality to the claimed system, specifically additional averaging that may be done to the *already-calculated* pressure ratios, and output to the display. *See, e.g.*, '463 Patent, cl. 30 (reciting a system "further configured to" calculate a pressure ratio across a plurality of cardiac cycles, calculate an average of the calculated pressure ratio for that plurality of cycles, and output the calculated average to the display). Like with the "calculate a pressure ratio claim term," Plaintiffs overextend the scope of the independent claims by trying to encompass subject matter that is added in the dependent claims. None of the dependent claims upon which Plaintiffs rely include limitations that fall within the scope of the respective independent claim and all depend on added limitations that were necessarily absent from the independent claims. Accordingly, the subject matter added in these dependent claims is presumed to not be present in the independent claims. *See Phillips*, 415 F.3d at 1314-15. Thus, Defendants' proposed construction is correct irrespective of the added limitations in the dependent claims and remains consistent with the claim language.

Therefore, the plain language of the claims demonstrate that what is "output, to a display" is the calculated pressure ratio, which is calculated only as average Pd / average Pa. Defendants' proposed construction aligns with the express claim language.

b. The specification is consistent with the claims and indicates that the calculated pressure ratio is limited to the explicitly claimed formula without additional steps.

The specification is rife with examples of the patentee defining mathematical equations with the phrase "calculated as" while separately describing the bases of an equation with the phrase "calculated based on". This terminology, which is reflected in the claim language, further indicates patentee's understanding that the pressure ratio is the explicit mathematical equation defined in the claims. For example, the '463 Patent discloses specific mathematical formulas throughout the specification. *See, e.g.*, '463 Patent, 15:11-21, 16:53-65, 27:67-28:1, 28:6-7. Each of these mathematical equations is preceded by the phrase "calculated as." *Id.* This can be juxtaposed with disclosures of calculations that utilize certain variables without explicitly defining how those variables are combined in a specific calculation. *See, e.g.*, *id.* at 12:26-29, 13:43-46, 31:4-5. Each of these general descriptions of the variables used in a calculation is preceded by the phrase "calculate[ed] [. . .] based on." *Id.*

The disclosures in the specification inform the meaning of the "pressure ratio" that is output to a display and "calculated as" average Pd / average Pa. *See Phillips*, 415 F.3d at 1315. Like each of the examples in the specification that provide a precise mathematical equation, the claim language likewise recites a specific equation of average Pd / average Pa. Any additional calculations or variables added to average Pd / average Pa would change the very nature of this claim element, resulting in something other than "the pressure ratio" which is output to the display. Accordingly, what is output to the display must be limited to the pressure ratio calculated only as average Pd / average Pa without additional calculations.

c. Patentee amended the claims to explicitly recite the pressure ratio calculation to overcome the prior art.

The final limitation of claim 1, reciting explicitly how the pressure ratio calculation is performed, was added during prosecution to overcome a prior art rejection. *See* Ex. A, Office Action Response (May 8, 2017) at 2-3. Where, as here, there is "particular prior art that the applicant is trying to distinguish," the prosecution history is particularly informative of claim meaning. *Lemelson v. Gen. Mills*, 968 F.2d 1202, 1205 (Fed. Cir. 1992). During an interview between patentee and the examiner, the examiner informed patentee that it needed to further define the calculated pressure ratio to overcome a prior art reference (Shalman):

> '[A] pressure ratio based on a plurality of distal pressure measurements . . . and a plurality of proximal pressure measurements' is broad enough to encompass Shalman's ratio that is indicative of pressure

> characteristics and which is 'based on' proximal and distal pressure measurements; Examiner suggested more clearly describing the ratio and/or the calculations.

Ex. A, Applicant Initiated Interview Summary (May 3, 2017). In response, patentee incorporated a dependent claim, which recited the explicit pressure ratio calculation as average Pd / average Pa, into the independent claim. *Id.* at Office Action Response (May 8, 2017) at 2-3. The examiner was persuaded by patentee's arguments and found that Shalman calculated pressure ratios "differently and are not compatible with averaging the measurements within [] a single window to find the averaged ratio over that window." *Id.* at Office Action (June 25, 2020) at 15. The specific pressure ratio calculation that was incorporated into the independent claims and distinguished over the prior art is the same explicit calculation defined in the claim language and specification as average Pd / average Pa.

The prosecution history of the '463 Patent "gives insight into what the applicant originally claimed as the invention, and [] what the applicant gave up in order to meet the Examiner's objections." *Lemelson*, 968 F.2d at 1205; *see also Phillips*, 415 F.3d at 1317 (holding the prosecution history is informative as to how "the inventor limited the invention in the course of prosecution"). Here, the prosecution history reveals that patentee initially drafted the claims to recite a pressure ratio "based on" proximal and distal pressures, with a separate dependent claim reciting the explicit calculation itself. *See generally* Ex. A. That dependent

claim, however, was rewritten in independent form—to overcome a prior art rejection—thereby foregoing the broader pressure ratio which may have been "based on" proximal and distal pressures but did not require an explicit calculation. *See Liebel-Flarsheim Co.*, 358 F.3d at 910 (holding courts cannot ignore limitations added or eliminated during prosecution). In arriving at the claimed "pressure ratio", the patentee abandoned "based on" for "calculated as." As such, the claimed "pressure ratio" that is "output, to a display" is both defined and bounded by the express formula in the claims.

d. Plaintiffs' efforts to impermissibly broaden the calculated pressure ratio should be rejected.

Although the claim language is clear, Plaintiffs seek to stretch the plain meaning to cover any number of calculations that could be performed so long as average Pd / average Pa is performed at some step. Plaintiffs are wrong for, at least, three reasons.

i. Plaintiffs' proposal impermissibly expands the claim scope including past the point of validity.

First, as Plaintiffs agree, the calculation is explicitly defined as average Pd / average Pa in the intrinsic record. *See* Sections IV.B.2.a-c, IV.A.1.a, IV.B.1.a, *supra*. Plaintiffs' proposal to leave the calculation open-ended, such that any number of other calculations could be included, far exceeds what is disclosed in the claim language, specification, and prosecution history. While Defendants do not

specifically address issues of validity at this stage, allowing the calculated pressure ratio to include variables and calculations other than average Pd / average Pa would leave the claims susceptible to written description and enablement challenges under 35 U.S.C. § 112 as additional calculations and variables are not contemplated by nor described in the specification. Because "claims should be so construed, if possible, as to sustain their validity," Defendants' proposed construction is more appropriate. *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999).

ii. Any number of additional calculations or techniques may be part of the claimed invention, but are not included within the calculated "pressure ratio".

Second, Defendants agree that any number of other calculations or techniques may be done before or after the calculation of a pressure ratio. As Plaintiffs emphasize, the specification contemplates a host of other processing, normalization, and refinement techniques that may be performed. *See* Section IV.B.1.b.ii, *supra* (listing normalization, filtration, temporal alignment, derivative-basis analysis, standard deviation calculations, and wave intensity analysis). None of these techniques, however, have any bearing on the manner in which the pressure ratio is calculated. According to the claim, it is the calculated pressure ratio (i.e., average Pd / average Pd) that is output to the display, not the results of a normalization, filtration, temporal alignment, derivative analysis, standard deviation, or wave intensity analysis.

Neither the claim language, nor Defendants' proposed construction, forecloses these other techniques from taking place when one uses the claimed system. These other techniques are not recited in the claim language and there is no requirement that every embodiment be represented by the claims. *See Baran*, 616 F.3d at 1316; *TIP Sys., LLC*, 529 F.3d at 1373; *Helmsderfer*, 527 F.3d at 1383; *PSN Ill.*, 525 F.3d at 1166; *see also SIMO Holdings, Inc. v. Hong Kong uCloudlink Network Tech. Ltd.*, 983 F.3d 1367, 1378-79 (Fed. Cir. 2021) (distinguishing *Oatey Co.*, 514 F.3d 1271 noting, despite the decision in *Oatey*, courts "should not infer that any particular embodiment is included in a claim when there is probative evidence that sufficiently indicates the contrary"). In fact, many of these techniques and portions of the specification cited by Plaintiffs have nothing to do with the calculation of a pressure ratio and occur in advance. *See, e.g.*, '463 Patent at 25:5-38 (describing analyses done to select the diagnostic window); 25:61-27:18 (temporal alignment occurs prior to pressure ratio calculation); 27:19-20 ("With the proximal and distal pressure measurements aligned, the pressure ratio for the diagnostic window 506 is calculated"). At base, none of these other techniques affect the "pressure ratio" which is the only value the independent claims require to be ultimately output to a display.

iii. An open-ended "pressure ratio" would fundamentally change the defined mathematical equation.

Third, construing the "pressure ratio" which is "output, to a display" to encompass any equation or technique that simply *includes* average Pd / average Pa would fundamentally change the recited claim element. Such a broad reading is an attempt to recapture what was given up during prosecution—a pressure ratio "based on" certain measurements. Plaintiffs hinge their overbroad understanding on the preamble of the independent claims because they are "comprising" claims. Plaintiffs' reliance on the preamble is misplaced. While a "comprising" claim may include within its scope unrecited structural elements, that principle cannot be used to change the recited claim elements themselves. *Cf. Crystal Semiconductor Corp.*, 246 F.3d at 1348 ("'[C]omprising' creates a presumption that the recited elements are only **a part of the device**, that the claim does not exclude additional, unrecited elements.") (emphasis added). For example, claim 1 may include within its bounds a device that also includes a third, unrecited pressure sensor; however, it cannot include a system which outputs a pressure ratio calculated in any manner other than average Pd / average Pa. A pressure ratio that is calculated in any manner other than average Pd / average Pa would not be the claimed pressure ratio.

Plaintiffs' proposed construction should be seen for what it is: an overbroad view of the claim language to ensnare as many would-be infringers as possible,

regardless of how those infringers perform their pressure ratio calculations. Defendants' proposed construction is the only construction fully in-line with the intrinsic record and proper reading of the claim language.

3. Plaintiffs' Reply Position

a. Defendants improperly seek to import negative limitations into the claims by construing "calculated as" as "calculated only as."

Plaintiffs explained in their Opening Brief that in the absence of language explicitly precluding additional processing steps, open-ended "comprising" claims like claims 1, 11, and 26 of the '463 patent are presumed to be open-ended. *See* Section IV.B.1.b.i, *supra* (collecting cases).

Defendants do not dispute that presumption but nonetheless seek to arbitrarily add the word "only" to the phrase "calculated as"—unjustifiably injecting a negative limitation into the claims to narrow them even further. *See* Section IV.B.2.a, *supra*; *see Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (holding that negative limitations must find support either in "the words of the claim" or through an "express disclaimer or independent lexicography in the written description that would justify adding that negative limitation." (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed. Cir. 2002))); *see also* Section IV.B.3.c, *infra* (regarding disclaimer). Yet Defendants cite to no case disputing that the use of "comprising" in the claims means the phrase "calculated

as" includes within its scope both additional calculations to produce the "pressure ratio" and additional processing after the calculation but before it is displayed. The overwhelming evidence in the intrinsic record also supports Plaintiffs' construction. *See* Section IV.B.3.b, *infra*.

i. Established case law permits the inclusion of additional processing steps before displaying the calculated pressure ratio.

In a factually analogous case, *SAIC v. United States*, the Court of Federal Claims rejected a similar argument involving "comprising" claims that recited elements in the order of "identify," "evaluate," and "display," which parallel the '463 patent's "receive," "calculate," and "output" limitations. 169 Fed. Cl. 643, 702 (2024); *see* '463 Patent, cls. 1, 11, 26. The court held that, even if claim steps involve a specific order, that does not require the claim elements "proceed immediately" through each claim limitation. *Id.* at 708. Rather, that "[l]ogic" can "require[] that some intervening event [] occur[] between the … operations to improve the accuracy" of the system. *Id.* at 702. What matters, the court emphasized, is that the claim elements undergo the "operation at some point" in sequence, even if that process includes intermediate or repeated steps. *Id.* at 708.

The same reasoning applies here. The '463 patent only requires that the calculations in the "calculated as" step take place. '463 Patent, cls. 1, 11, 26. The claims do not, for example, preclude the so-calculated pressure ratio from

subsequently being rounded to two decimal places to fit on a display or from being color-coded based on the confidence level, as the '463 patent expressly describes. *Id*., 30:59-31:3, 30:32-33. "Intervening events" in between the initial calculation of a pressure ratio and the display thereof are expressly contemplated to maintain accuracy. *SAIC*, 169 Fed. Cl. at 702; *Id*., 27:27-32 ("[A]ccuracy of the pressure ratio can be improved by performing the pressure ratio calculations over multiple cardiac cycles and averaging the values and/or using an analysis technique to identify one or more of the calculated values that is believed to be most and/or least accurate."); *see also id.*, cls. 26-32. These are just a few non-limiting examples in the '463 patent confirming that Defendants' construction is contrary to the intrinsic record. By failing to point to any intrinsic evidence that explicitly instructs otherwise, Defendants fail to overcome the presumption that the claims are open and allow for additional processing.

ii. The dependent claims confirm the pressure ratio calculations are open-ended.

As discussed in the Opening Brief, Defendants' construction is inconsistent with the dependent claims, which expressly *require* additional processing before displaying the calculated pressure ratio. *See* Section IV.B.1.b.iii, *supra*. So, instead, Defendants try to argue that the dependent claims *add* additional scope to the independent claims rather than further limit them. *See* Section IV.B.2.a, *supra*. As with the "calculate a pressure ratio," term, this logic gets it backwards—additional

limitations in a dependent claim further limit the independent claim, not the other way around. *See* Section IV.A.3.a, *supra*.

The dependent claims recite "*the* pressure ratio," confirming that the same ratio defined in the independent claims is the one being further limited—not replaced or redefined. For example, dependent claim 32 recites: "output the calculated average to the display only when the difference is below a threshold value"—where the "average" is calculated from "*the* calculated pressure ratio" across "a plurality of cardiac cycles." *See* '463 Patent, cls. 28-32. Claim 32 plainly imposes a condition on when "*the* pressure ratio" is displayed, which is by definition an additional processing step. Each set of dependent claims refer back to "*the* pressure ratio"—a singular term with a clear antecedent. *Id*., cls. 20-22, 28-30. To suggest otherwise is to rewrite the claims and create a phantom element that does not exist. *Hewlett-Packard Co. v. Mustek Sys.*, 340 F.3d 1314, 1325 (Fed. Cir. 2003) (Courts "cannot construe the claim to add a limitation not present in the claim itself.").

As discussed for the previous term, Federal Circuit precedent confirms that the phrase "further configured to" merely adds specificity to the limitations recited in the independent claims and does not newly introduce otherwise unclaimed steps. *See* Section IV.A.3.a, *supra*; *see Koninklijke KPN N.V.*, 942 F.3d. at 1150. This conclusion is reinforced even under Defendants' own logic. Defendants argue that "further configured to" denotes a separate element outside the scope of the

independent claims, yet their interpretation is inconsistent with the structures of the dependent claims themselves. Particularly, all dependent claims that "output" the processed pressure ratio use only the phrase "configured to," as opposed to "*further* configured to"—reinforcing that these claims modify the output of "*the* pressure ratio" in the independent claims.

Moreover, Defendants still offer no explanation for why "the pressure ratio" in the independent claims must necessarily preclude additional processing steps, while "the pressure ratio" in the dependent claims may undergo post-processing. *Intelligent Automation Design*, 799 F. App'x at 850 (holding that the same claim term should be construed consistently across claims). In addition to being internally inconsistent, this interpretation should be rejected because, as discussed below, the intrinsic evidence does not support any such distinction.

b. Defendants ignore numerous embodiments in the specification that expressly include processing steps that occur before, during, and after pressure ratio calculations.

Defendants' argument that permitting additional processing steps would fundamentally alter the recited claim elements is incorrect and inconsistent with the law. *See* Section IV.B.2, *supra*. While it is true that "comprising" claims are inclusive of unrecited elements, they also cover **unrecited features** within a claim element. *Promega Corp. v. Life Techs. Corp.*, 773 F.3d 1338, 1350 (Fed. Cir. 2014), *rev'd and remanded*, 580 U.S. 140 (2017) ("open claims 'embrace technology that may *add*

features to devices otherwise within the claim definition'" (citing *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed. Cir. 2005) (emphasis added))).

Defendants' limiting construction is a transparent attempt to carve out any diagnostic method that performs so much as a single processing step to the "calculated pressure ratio"—thereby creating a trivial roadmap to circumvent infringement. Illustratively, under Defendants' construction, the calculated pressure ratio must be a single-cycle, raw, unrounded, unnormalized, unfiltered, and unprocessed value that cannot face temporal alignment, baseline correction, signal smoothing, or outlier rejection—and what is displayed must be exactly that: without averaging, thresholding, scaling, or even simple formatting such as visual framing, annotations, or color-coding—because it is "calculated as" and nothing else.

Defendants' unreasonably limiting construction is also clearly contradicted by the teachings in the specification. For example, if Defendants' construction were adopted, even the most basic processing steps, such as rounding the ratio to two decimal places, would be prohibited—despite that exact operation being disclosed by the patent. *See* '463 Patent, 30:32-33 ("The pressure ratio value is typically expressed to two decimal places"). Equally unreasonable, a copycat infringer who replicates the system in its entirety could attempt to avoid literal infringement simply by adding .00001 to Pd/Pa—a value that would not meaningfully affect assessing stenoses. *Lee v. Mike's Novelties, Inc.*, 543 F. App'x 1010, 1015 (Fed. Cir. 2013)

(holding that "infringement cannot be avoided by adding another feature that contributes to" a claim element's functionality, where the element is already sufficient to perform that function without the additional feature).

In addition to these obvious implications, Defendants' construction reads out clear disclosure of processing steps performed at various stages of the claimed system, particularly with regard to additional processing that may occur during the calculation *or* output of the pressure ratio.

Prior to calculation, the specification describes pre-processing techniques such as aligning proximal and distal pressure measurements, applying signal processing techniques to assist with selecting the diagnostic window, storing measurement data for later use, temporally shifting measurements to ensure they fall within the same window, and normalizing values to ensure consistency. '463 Patent, 13:57-64, 14:29-36, 14:57-60, 25:41-26:33, 27:7-21, 28:38-46.

While the pressure ratio is being calculated, the system may average slopes of the pressure measurements, iteratively compare pressure ratio values against a threshold, or assess a confidence level which prompts further calculations if needed. *Id*., 28:47-29:27, 29:28-49, 30:17-33.

The specification also includes post-calculation processing steps, such as delaying display of the ratio until it is deemed "stable," averaging multiple calculated ratios, applying a scale factor, rounding the ratio to two decimal places,

and color coding the pressure ratio as the confidence level changes which may be displayed alongside a sliding scale or bullseye. *Id*., 27:23-32, 28:11-21, 30:18-22, 30:32-33, 30:40-56, 30:59-31:3.

Each of these added steps confirms that additional calculations and processing are not only contemplated but encouraged for some applications. Therefore, in light of the multiple layers of processing disclosed, the claims' "calculate" and "output" steps should be construed as open-ended. *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007) (rejecting proposed claim constructions that would exclude disclosed embodiments in the specification).

c. Defendants cannot identify clear disclaimer of additional processing to the pressure ratio during prosecution to support limiting the claim to "calculated only as."

i. Overview of the '463 patent prosecution history.

Defendants contend that by amending the independent claims to include a limitation initially presented in a dependent claim—"wherein the pressure ratio is calculated as an *average*"—patentee bounded the claims to the express formula recited over a single cardiac cycle and nothing more. *See* Sections IV.A.2.c, *supra,* IV.B.2.c, *supra*. A review of the prosecution history from start to end reveals that the amendments and statements Defendants rely on were, again, taken out of context.

In the first Office Action, Examiner issued several rejections under 35 U.S.C. §§ 102 and 103, primarily relying on references to Manstrom and Shalman. The Examiner asserted that Manstrom disclosed a pressure ratio but did not disclose the selection of a diagnostic window, which the Examiner instead contended was taught by Shalman. Ex. H, Office Action (July 14, 2016). In an Applicant-Initiated Interview, the Applicants clarified that, although Manstrom may disclose a pressure ratio Pd/Pa, it did so solely in the context of Fractional Flow Reserve or "FFR," which was an older prior art method requiring "the use of hyperemic agents." Ex. I, Applicant Initiated Interview Summary (Aug. 25, 2016); *see* Section II. B, *supra* (giving an overview of FFR).

Applicants' subsequent Office Action Response further explained that even if it happened to involve proximal and distal blood pressure measurements, Shalman—which disclosed a "Pulse Transmission Coefficient" rather than a pressure ratio—was not applicable or transferable to Manstrom's FFR. *See* Ex. F, Office Action Response (Sept. 13, 2016) at 9 ("Shalman discloses … Pulse Transmission Coefficient (E) based on the energy of the high frequency components of the dicrotic notches of proximal and distal pressure pulses."). Shalman's "'PTC(E)' quantif[ies] a *change in the shape* of the dicrotic notch of a distal pressure pulse with respect to the dicrotic notch of a proximal pressure pulse" by taking the "high frequency component of the dicrotic notch" for both, which is computed by "the standard

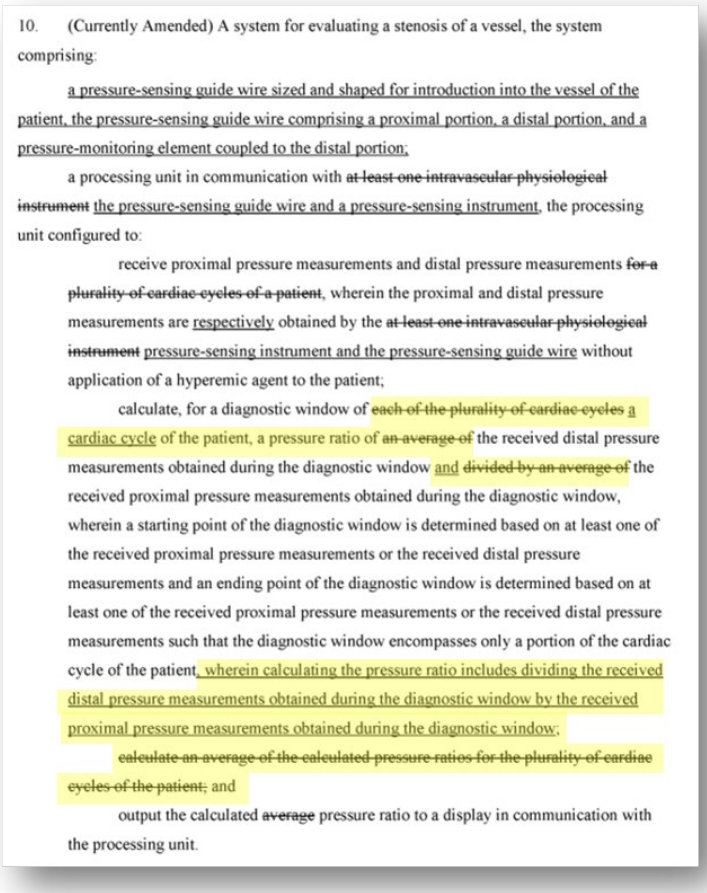
deviation of dP(t) where dP(t) = P(t) – Plow(t).” *See* Ex. O, Shalman et al., [0027]. Applicants explained these differences in their response. *See* Ex. F, Office Action Response (Sept. 13, 2016).

In the second Office Action, the Examiner again issued rejections under §§ 102 and 103, this time relying primarily on Shalman, having found Applicants arguments regarding Manstrom “persuasive.” Ex. G, Office Action (Jan. 11, 2017) at 11. In discussing allowable subject matter, the Examiner stated claim 7—which recited “calculate a pressure ratio calculated as an average of the plurality of distal pressure measurements in the window divided by an average of the plurality of proximal pressure measurements in the window”—“would be allowable if rewritten in independent form including all the limitations of the base claim.” *Id*. The “Examiner agree[d] that Shalman **does not disclose a ratio between two pressure values**,” though he asserted that a pressure ratio “based on” two pressure values was “broad enough to encompass Shalman’s ratio.” Ex. J, Applicant Initiated Interview Summary (May 3, 2017) (emphasis added). Notably, the Examiner also “agreed that reciting ‘**calculate a ratio of** distal pressure measurements to proximal pressure measurements **based on/using a plurality of pressure measurements** obtained during the diagnostic window …’ **would be sufficient to overcome Shalman**.” *Id* (emphases added).

Therefore, in the following Office Action Response and "in the interest of moving [the] case to allowance expediently," Applicants amended claim 7 as proposed by Examiner and revised claim 10 to include the agreed-upon language from the interview ("calculate [] a pressure ratio of an average…"). Ex. K, Office Action Response (May 8, 2017) at 7. In so doing, Applicants maintained that "Shalman does not disclose or suggest calculating 'a pressure ratio.' In fact, Shalman is focused on calculating parameters that are '*substitutes* to the clinically accepted Fractional Flow Reserve' pressure ratio" (i.e., Pd/Pa). *Id.* (emphasis added).

Following these amendments, the Examiner issued only § 101 rejections and acknowledged that "the prior art of record fails to anticipate or make obvious" the claimed invention which differs from Shalman because, again, "Shalman's pressure ratios are calculated differently and are not compatible with" the claimed invention. Ex. D, Office Action (Sept. 19, 2017) at 4. Applicant again amended the claims, this time to address § 101 rejections. *See* Ex. B, Office Action Response (Dec. 19, 2017) at 15-16 (claim 10). In doing so, Applicants moved the "plurality of cardiac cycles" limitations from claim 10 to a dependent claim, which in turn required replacing the "calculate a pressure ratio of *averages*" language which was substituted with "wherein calculating the pressure ratio includes *dividing* the received [] pressure measurements …"—still different from claim 7, which recited "wherein the pressure

ratio is calculated as an *average* of the plurality of [] pressure measurements." *See id.* (emphasis added).



10. (Currently Amended) A system for evaluating a stenosis of a vessel, the system comprising:

a pressure-sensing guide wire sized and shaped for introduction into the vessel of the patient, the pressure-sensing guide wire comprising a proximal portion, a distal portion, and a pressure-monitoring element coupled to the distal portion;

a processing unit in communication with ~~at least one intravascular physiological instrument~~ the pressure-sensing guide wire and a pressure-sensing instrument, the processing unit configured to:

receive proximal pressure measurements and distal pressure measurements ~~for a plurality of cardiac cycles of a patient~~, wherein the proximal and distal pressure measurements are respectively obtained by the ~~at least one intravascular physiological instrument~~ pressure-sensing instrument and the pressure-sensing guide wire without application of a hyperemic agent to the patient;

calculate, for a diagnostic window of ~~each of the plurality of cardiac cycles~~ a cardiac cycle of the patient, a pressure ratio of ~~an average of~~ the received distal pressure measurements obtained during the diagnostic window and ~~divided by an average of~~ the received proximal pressure measurements obtained during the diagnostic window, wherein a starting point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements and an ending point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements such that the diagnostic window encompasses only a portion of the cardiac cycle of the patient, wherein calculating the pressure ratio includes dividing the received distal pressure measurements obtained during the diagnostic window by the received proximal pressure measurements obtained during the diagnostic window;

~~calculate an average of the calculated pressure ratios for the plurality of cardiac cycles of the patient;~~ and

output the calculated ~~average~~ pressure ratio to a display in communication with the processing unit.

Id. The Examiner ultimately found the issued claims patentable over Shalman after the Applicants added the "wherein" clause that added back the step of *averaging* the received pressure measurements as opposed to merely *dividing* them. Ex. E, Notice of Allowance (Oct. 5, 2020). This was because after the Applicant "removed" the averaging language from the claims, "it [was] not clear if the distal measurements are all somehow combined and the proximal measurements are all somehow

combined and then a single act of division is performed." *See* Ex. L, Office Action (June 25, 2020) at 3, 14.

Bottom line: the Examiner never relied on Shalman for any additional calculations or processing to which Applicants needed to distinguish, nor did Applicants ever distinguish Shalman on those grounds. The Applicants instead explained that Shalman does not calculate *any kind* of pressure ratio. *See* Ex. K, Office Action Response (May 8, 2017) at 7. Also, up to their final correspondences, neither Applicants nor Examiner distinguished between the different phrasings that preceded the averaging language which overcame the prior art—"calculate … a pressure ratio of an average" and "calculated as an average." *See* Ex. M, Office Action Response (Sept. 21, 2020); Ex. N, Applicant Initiated Interview Summary (Aug. 28, 2020). The amendments were simply made to expedite allowance by harmonizing claim 10 with claim 7 without any discussion at any point by the parties regarding whether the phrasing was, or needed to be, open or close-ended.

ii. Patentee did not surrender additional calculations or processing steps during prosecution.

The inventors did not surrender the possibility of additional processing to the calculated pressure ratio, or anywhere else in the claims for that matter, nor did they have to. This is not a case where the prior art disclosed "Pd/Pa + X" or "Pd/Pa × X", and Applicant distinguished their claimed ratio as only Pd/Pa. *Cf. Shire Dev., LLC v.*

Watson Pharms., Inc., 787 F.3d 1359, 1365 (Fed. Cir. 2015) (finding that prosecution disclaimer applied where the applicant "distinguish[ed] the claimed invention over the prior art" hence, "indicating what the claims do not cover."). In fact, one embodiment the claims cover is "Pd/Pa – X", X being another pressure ratio used to determine if the calculated ratio is below or above a set threshold value before displaying it. *See* '463 Patent, cls. 31-32.

Markedly, at every stage of prosecution, both Applicant and Examiner consistently recognized that the computations disclosed in Shalman were fundamentally different from the claimed pressure ratio. Faced with a broad range of rejections, Applicant trialed different language, including "ratio based on dividing," "ratio includes dividing" "ratio of an average" and "ratio [] calculated as an average." *See generally* Ex. F, Office Action Response (Sept. 13, 2016); Ex. K, Office Action Response (May 8, 2017); Ex. B, Office Action Response (Dec. 19, 2017). At a minimum, none of these linguistic changes were made to preclude additional processing. *See N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1293-95 (Fed. Cir. 2000) (holding that prosecution disclaimer did not "support the judicial narrowing of a clear claim term" because the inventors' statements were amenable to multiple reasonable interpretations).

More importantly, in each and every communication between the Applicant and the United States Patent and Trademark Office, *not once* did the parties ever

discuss additional processing steps, whether that be their inclusion or lack thereof. The concept of precluding such processing simply never arose—unsurprisingly so, given that Shalman's methods are entirely different, a distinction echoed by the parties at nearly every step during prosecution. *Comput. Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374-75 (Fed. Cir. 2008) ("The doctrine of prosecution disclaimer 'protects the public's reliance on definitive statements made during prosecution' by 'precluding patentees from recapturing through claim interpretation specific meanings [clearly and unmistakably] disclaimed during prosecution.'" (citing *Omega Eng'g*, 334 F.3d at 1323-23)). For all the reasons set forth above, patentee cannot be seen to have clearly and unequivocally surrendered the claimed pressure ratio with additional processing steps and therefore Defendants have no basis to narrow the claims and chosen language to "calculated only as."

4. Defendants' Sur-Reply Position

Once again, the parties agree that the pressure ratio which is output to a display is calculated in the manner recited in the claims. Moreover, as Defendants made clear in their Answering Brief, the parties also agree that other processing (before, during, or post-pressure ratio calculation) can occur. What Plaintiffs miss, however, is that none of these other processes affect how the pressure ratio is calculated, which is what is ultimately output to the display. Similarly, Plaintiffs ignore, intentionally or otherwise, the explicitly-recited calculation that was added

during prosecution because the original calculation being "based on" pressure measurements was not valid over prior art. Turning instead to an infringement and prosecution history estoppel and disclaimer analysis, Plaintiffs' argument supporting their proposed construction for this term misses the mark.

a. Other processes may be performed as part of the claimed system, but they are not part of the explicitly-defined calculated pressure ratio that is output to a display.

The plain language of the claims recite that what is output to a display is a calculation: average Pd / average Pa during a diagnostic window. Defendants' proposed construction aligns with the claim language where the pressure ratio is calculated only as average Pd / average Pa. *See* Section IV.B.3.a, *supra*. What Plaintiffs refer to as a "negative" limitation is merely inherent in the claim language—a pressure ratio "***calculated as***" average Pd / average Pa cannot include additional calculations. *Cf. Omega Eng'g, Inc.*, 334 F.3d at 1323. If it did, it would become an entirely different pressure ratio which does not fall within the meaning of the claims. A calculation, like the pressure ratio recited in the '463 Patent, is meaningfully different from an apparatus or method which may include additional structures or steps without transforming the essence of that apparatus or method. The claimed system for evaluating a stenosis may include additional processing—as urged by Plaintiffs—but those other processes do not alter the calculation of the pressure ratio itself as defined by the claim.

Nevertheless, Plaintiffs extensively argue that various processes are disclosed in the specification and dependent claims and, therefore, must, or at least can, become part of the calculated pressure ratio. *See* Section IV.B.3.b, *supra*. Plaintiffs' own descriptions of those processes, however, belie their argument. For example, Plaintiffs point to "**pre-processing** techniques" including "storing measurement data," as well as comparisons done "**[w]hile** the pressure ratio is being calculated," and lastly "**post-calculation** processing steps" like displaying, averaging, and rounding. *See* Section IV.B.3.b, *supra* (emphasis added). By definition, none of these processes affect the calculation of the pressure ratio. The claim language, and specification, recite one explicit way of calculating the pressure ratio (average Pd / average Pa) and any other processes that occur have no impact on this calculation.

Thus, the potential inclusion of these processing techniques has no bearing on the claim construction of the calculated pressure ratio which is output to the display. Plaintiffs point to the *SAIC* case as purportedly "factually analogous." *See* Section IV.B.3.a.i, *supra*. While Defendants do not see the similarities[5], Plaintiffs' spotlight on this case highlights their misunderstanding of this claim term. Just as in *SAIC*, "intervening event[s]" could certainly occur between the steps of the claims. 169 Fed. Cl. at 702. As explained, pre-processing and post-calculation activities such

[5] Notably, Plaintiffs have referenced a decision pertaining to a Motion in Limine and unrelated to the claim construction process.

as normalization, threshold comparisons, averaging, and additional displays may occur. None of these intervening events affect the pressure ratio calculation (indeed, some explicitly occur "post-calculation"). *See* Section IV.B.3.b, *supra*. Indeed, any type of rounding to a certain decimal place, as Plaintiffs suggest, can occur ***after*** the pressure ratio calculation is complete.[6]

Continuing with their reliance on "additional processing," Plaintiffs argue the dependent claims broaden the meaning of the claimed calculated pressure ratio. *See* Section IV.B.3.a.ii, *supra*. The meaning of "the pressure ratio" is consistent across all claims and no processes that impose conditions, calculate additional averages, or compare to threshold values alter the initial pressure ratio calculation.

At base, Defendants have no need to "overcome the presumption that the claims are open and allow for additional processing." *See* Section IV.B.3.a.ii, *supra*. Defendants agree these are "comprising" claims and that other processes may occur before, during, or after the claimed step requiring the pressure ratio be calculated and output to a display. None of these possibilities negate that the explicitly-recited pressure ratio is "calculated as" average Pd / average Pa during the diagnostic

[6] Under the guise of claim construction, Plaintiffs actually appear to be making infringement and doctrine of equivalents arguments to encourage a rewriting of the claim language.

window. No other variables, multipliers, or additional calculations are included within the meaning of this term.

b. The specification and prosecution history illustrate the juxtaposition between a pressure ratio "based on" certain variables and a pressure ratio "calculated as" average Pd / average Pa.

Along with providing the explicit pressure ratio calculation (average Pd / average Pa), the independent claims also teach that this pressure ratio is, more broadly, "based on" distal and proximal pressure measurements. *E.g.*, '463 Patent, cl. 1. These different terms—"calculated as" and "based on"—have different meanings and provide different bounds for the recited pressure ratio output to the display. *See CAE Screenplates*, 224 F.3d at 1317; *see also* Section IV.B.2.b, *supra* (describing how the specification differentiates between a mathematical formula ("calculated as") and variables used in a calculation ("based on")). Plaintiffs now ignore the limitation precisely reciting that the pressure ratio is "calculated as" average Pd / average Pa and instead hope to have the Court leave it open-ended as if "based on" distal and proximal measurements was the claim term.

The important difference between "calculated as" and "based on" is also borne out in the prosecution history. Plaintiffs provide a 7-page tangent describing the prosecution history of the '463 Patent and claim amendments pertaining to the pressure ratio calculation. *See* Section IV.B.3.c, *supra*. Buried within this summary, however, is the key: "Examiner agree[d] that Shalman **does not disclose a ratio**

between two pressure values" but believed a recited pressure ratio "based on" two pressure values was not enough to get around Shalman, the relevant prior art. *See* Section IV.B.3.c, *supra* (emphasis in original) (citing Ex. J). Once patentee amended the claim language to avoid Shalman by explicitly reciting a pressure ratio "calculated as" average Pd / average Pa, the examiner determined "Shalman's pressure ratios are calculated differently." *See* Section IV.B.3.c, *supra* (citing Ex. D). Plaintiffs are, therefore, wrong to suggest that Applicants did not need to alter the claim language to distinguish the claimed pressure ratio over the prior art. Regardless of whether the amendment was made to expedite prosecution, the result is the same: "calculated as" is different from "based on." *See also Genzyme*, 315 F. Supp. 2d at 583.

Naturally, a pressure ratio that is calculated "based on" certain averaging of variables may include other variables, multipliers, or calculations. However, the same cannot be said of a pressure ratio "calculated as" average Pd / average Pa. The distinction between these terms and their scope is telling and even Plaintiffs recognize that "[t]he plain language of the claims unambiguously describes the way in which 'a pressure ratio,' is 'calculate[d],' giving the term metes and bounds for how the calculation is performed." *See* Section IV.A.1.a, *supra*.

V. CONCLUSION

A. Plaintiffs' Conclusion

For the foregoing reasons, the Court should reject Defendants' constructions and adopt Plaintiffs' proposed constructions.

B. Defendants' Conclusion

For the foregoing reasons, Defendants' proposed constructions should be adopted by the Court.

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